

Registration No 62097-27

NEW APPLICATIONS

DATE: SEP 29 2011

FILE NUMBER: 62097-ET

FEP (OPPIN ENTRY) LV SEP 29 2011
(Initial & date)

FILE ROOM: _____
(Initial & date)

SIG: _____
(Initial & date)

FILE ROOM: _____
(Initial & date)

✓ ASSIGN TO PM 9/1 (NO DATA)

 JACKET TO SHELF (DATA)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Frederick T. Smith
Fine Agrochemicals Ltd.
c/o SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

JAN 27 2014

Subject: Storage Stability and Corrosion Characteristics Studies
Product Name: Indolebutyric Acid Technical
EPA Reg. No: 62097-27
Your Submission Dated August 6, 2013

Dear Mr. Smith:

The Biopesticide and Pollution Prevention Division (BPPD) has received and reviewed the application referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, and the Pesticide Registration Improvement Act (PRIA 3). BPPD has concluded that your application is not acceptable and the identified deficiencies must be addressed before we will consider the terms of registration of this product satisfied. The deficiencies in your application are listed in the Confidential Attachment to this letter.

Should you have any questions regarding this action, you may contact Gina Burnett at (703) 605-0513 or via email at burnett.gina@epa.gov.

Sincerely,

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Attachment: Confidential Appendix

		CONCURRENCES						
SYMBOL	▶ 7511P							
SURNAME	▶ Burnett							
DATE	▶ 1/23/14							

EPA Form 1320-1A (1/80)

OFFICIAL FILE COPY

CONFIDENTIAL APPENDIX

The studies contained in MRID 49192001 and intended to satisfy the requirements of Storage Stability (OCSPP Guideline No. 830.6317) and Corrosion Characteristics (OCSPP Guideline No. 830.6320) for Indolebutyric Acid Technical (EPA Reg. No. 62097-27) were conducted under accelerated conditions (14 days) at elevated temperature (54°C). Although the OCSPP Test Guidelines indicate that test conditions may be expanded to include accelerated conditions at elevated temperatures, these data alone cannot satisfy the data requirements. **You must submit one (1) year Storage Stability (OCSPP Guideline No. 830.6317) and Corrosion Characteristics (OCSPP Guideline No. 830.6320) studies to address the data requirements.**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: November 7, 2013

SUBJECT: Storage Stability and Corrosion Characteristics Studies for Indolebutyric Acid Technical (EPA Reg. No. 62097-27) Containing 99.7% of Indole-3-Butyric Acid (IBA) as its Active Ingredient (A.I.).

Decision Number: 482172
DP Number: 414410
EPA File Symbol Number: 62097-27
Chemical Class: Biochemical
PC Code: 046701
CAS Number: 133-32-4
Active Ingredient Tolerance Exemptions: 40 CFR § 180.1158
MRID Numbers: 49192001
Type of Review: Product Chemistry

FROM: Colin G. Walsh, M.S., Biologist /s/ 11/07/2013
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

A handwritten signature in black ink, appearing to read "Colin Walsh", is written over the "FROM:" line.

TO: Gina Burnett, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

On behalf of Fine Agrochemicals, Ltd., SciReg, Inc., has submitted Storage Stability (OCSP Guideline No. 830.6317) and Corrosion Characteristics (OCSP Guideline No. 830.6320) studies for Indolebutyric Acid Technical (EPA Reg. No. 62097-27) in MRID 49192001. The studies were submitted under cover letter dated 08/06/2013 and are in response to a term of registration listed on the Notice of Pesticide Registration dated 09/17/2012.

RECOMMENDATIONS AND CONCLUSIONS

1. The product chemistry submission is **UNACCEPTABLE**.

MRID 49192001: UNACCEPTABLE

- a. The registrant did not adequately address the Storage Stability (OCSPP Guideline No. 830.6317) and Corrosion Characteristics (OCSPP Guideline No. 830.6320) data requirements. Although the OCSPP Test Guidelines indicate that test conditions may be expanded to include accelerated conditions at elevated temperatures, these data alone cannot satisfy the data requirements. The registrant must submit one (1) year Storage Stability (OCSPP Guideline No. 830.6317) and Corrosion Characteristics (OCSPP Guideline No. 830.6320) studies to address the data requirements.

SUMMARY OF DATA SUBMITTED

Product Chemistry (MRID 491920101)

Refer to Table 1 below for the physical and chemical characteristics data submitted for Indolebutyric Acid Technical (EPA Reg. No. 62097-27).

TABLE 1. Physical and Chemical Properties for Indolebutyric Acid Technical (40 CFR § 158.2030)		
OCSPP Guideline Reference No./Property	Description of Result	MRID
830.6317 Storage Stability	Stable at 54°C for 14 days. UNACCPETABLE.	49192001
830.6320 Corrosion Characteristics	No corrosion observed at 54°C for 14 days. UNACCPETABLE.	49192001

The registrant submitted Storage Stability and Corrosion Characteristics data under accelerated conditions (14 days) at elevated temperature (54°C). The data indicate that Indolebutyric Acid Technical (EPA Reg. No. 62097-27) is stable under the accelerated conditions at elevated temperature and no corrosion was observed on the packaging. On Day 0, the average a.i. concentration of IBA was 99.67%. On Day 14, the average a.i. concentration of IBA was 100.04%. No changes to the packaging, except for slight changes in weight, were observed in the 14 day test at elevated temperature. The changes in weight averaged 0.46% and 0.63%.

Although these stability and corrosion characteristics indicate that the test substance is stable and non-corrosive under accelerated conditions at elevated temperature, these data **do not** satisfy the Storage Stability (OCSPP Guideline No. 830.6317) and Corrosion Characteristics (OCSPP Guideline No. 830.6320) data requirements. As indicated in the OCSSP Test Guideline for Storage Stability, OCSPP Guideline No. 830.6317, Section (b)(2)(iv)(C), "The test parameters

IBA
PC Code: 046701
Type of Review: Product Chemistry

DP Number: 414410
EPA File Symbol No.: 62097-27

may be expanded to include accelerated conditions, such as elevated temperature (or 40 °C-54 °C) or cold temperature extremes (-20 °C-0 °C)." Although the OCSPP Test Guidelines indicate that test conditions may be expanded to include accelerated conditions, these data alone cannot satisfy the data requirements. Therefore, you must submit one (1) year Storage Stability (OCSPP Guideline No. 830.6317) and Corrosion Characteristics (OCSPP Guideline No. 830.6320) studies to address the data requirements.

NO DERS WERE WRITTEN FOR THIS REVIEW

cc: Colin G. Walsh, Gina Burnett, BPPD Science Review File, IHAD/ARS, Colin G. Walsh, FT, PY-S, November 7, 2013

DATA PACKAGE BEAN SHEET

Date: 26-Aug-2013

Page 1 of 2

Decision #: 482170

DP #: (414417)

NON PRIA

Parent DP #:

Submission #: 939375

E-Sub #:

*** Registration Information ***

Registration: 62097-26 - KINETIN TECHNICAL

Company: 62097 - FINE AGROCHEMICALS, LTD

Risk Manager: RM 91 - Gina Burnett - (703) 605-0513 Room# PY1 S-8946

Risk Manager Reviewer: Gina Burnett GBURNETT

Sent Date: 07-Aug-2013

PRIA Due Date: 24-Nov-2013

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (575) CONDITIONAL REGISTRATION FOLLOW-UP;DATA REQUIRED;REQUIRES SCIENCE

Ingredients: 116801, Cytokinin (as kinetin)(99%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 26-Aug-2013

Due Back: 10/26/2013
GB

DP Ingredient: 116801, Cytokinin (as kinetin)

DP Title: _____

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: BPPD / BPB

Last Possible Science Due Date: 15-Sep-2013

Team Name: RM 91

Science Due Date: _____

Reviewer Name: Colin

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Russ,

Please assigned this Storage Stability, Corrosion Characteristics, and stability to normal and elevated temperatures data for review. If you would like to give it to Sadaf, all she needs to do is pull 49192101 and 49192102 from documentum. You or I could scan and send her the cover letter, label and CSF.

BPB Reviewer please complete by Oct 26, 2013.

Thanks,
Gina

DP#: (414417)

*** Studies Sent for Review ***

Decision#: (482170)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49192101		Kaminsky, M. (2013) Kinetin Technical Product Chemistry. Project Number: 17323/13. Unpublished study prepared by Stillmeadow, Inc. 15p.	830.6313/Stability to normal and elevated temperatures, metals, and metal ions	Pass (13-Aug-2013)
49192102		Kaminsky, M. (2013) Kinetin Technical Accelerated Storage Stability with Corrosion Characteristics. Project Number: 17324/13. Unpublished study prepared by Stillmeadow, Inc. 19p.	830.6317/Storage stability	Pass (13-Aug-2013)
49192102		Kaminsky, M. (2013) Kinetin Technical Accelerated Storage Stability with Corrosion Characteristics. Project Number: 17324/13. Unpublished study prepared by Stillmeadow, Inc. 19p.	830.6320/Corrosion characteristics	Pass (13-Aug-2013)

SciReg, Inc.
Science and Regulatory Consultants

August 6, 2013

Ms. Linda Hollis
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

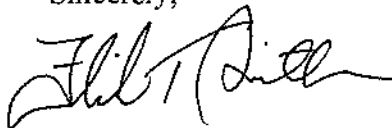
Re: Indolebutyric Acid Technical (EPA Reg. No. 62097-27)
- Storage stability/corrosion characteristics study

Dear Ms. Hollis:

In response to the Agency's September 17, 2012 conditional registration notice, on behalf of Fine Agrochemicals Ltd., enclosed please find three copies of an accelerated storage stability and corrosion characteristics study to support registration of Indolebutyric Acid Technical (EPA Reg. No. 62097-27).

Should you have any questions, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

TRANSMITTAL DOCUMENT

Submitter

Fine Agrochemicals Ltd.
Hill End House
Whittington
Worcester WR5 2RQ
United Kingdom

SciReg, Inc.*
12733 Director's Loop
Woodbridge, VA 22192

* SciReg, Inc. is the authorized agent for Fine Agrochemicals Ltd.

Regulatory action in support of which this package is submitted

Product Registration:
Indolebutyric Acid Technical (EPA Reg. No. 62097-27)

Transmittal Date

August 6, 2013

Contents

Volume I Administrative Materials

49192001 Volume 2 Accelerated Storage Stability and Corrosion Characteristics (OPPTS
830.6317 and 830.6320)

Company Official: Frederick T. Smith



Company Name: SciReg, Inc.

Company Contact: Frederick T. Smith (703) 494-6500; fsmith@SciReg.com



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 62097-27	2. EPA Product Manager L. Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Indolebutyric Acid Technical	PM# 91	
5. Name and Address of Applicant (Include ZIP Code) Fine Agrochemicals Ltd. Hill End House Whittington, Worcester WR5 2RQ UK <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of storage stability and corrosion characteristics data.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Package wgt	No. Per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Frederick T. Smith	Title Agent	Telephone No. (Include Area Code) (703) 494-6500	
Certification I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Agent (SciReg, Inc.)		
4. Typed Name Frederick T. Smith	5. Date 8/6/13		

Material Sent for Data Extraction

Reg. # 62097-27Description: Indolebutyric Acid Technical☒ Material(s) Sent to Data Extraction Contractors:☐ New Stamped Label Dated _____☒ Notification Dated Nov. 15, 2012 (Accepted)☐ New CSF(s) Dated _____☐ Other: _____☐ Decision #: _____☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Sylvester GeorgePhone: (703) 603-0688 Division: BPRDDate: Nov. 26, 2012

Cloned in OAH



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 26, 2012

SciReg Inc.
12733 Director's Loop
Woodbridge, VA 22192
Attn: Frederick T. Smith

Subject: Notification of additional container sizes consistent with the provisions of PR Notice 98-10.

Product name: Indolebutyric Acid Technical.

EPA Reg. No: 62097-27.

Additional container sizes: 1, 5, and 7.5 pounds.

Your Submission dated November 15, 2012.

Dear Mr. Smith:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 98-10 dated above. A screen of this request has been conducted for its applicability under PRN 98-10, and it has been determined that the action requested falls within the scope of this Notice. Our records have been duly noted, and the application, EPA Form 8750-1 submitted has been stamped "Notification Accepted" and will be placed accordingly in our records.

Three (3) copies of final printed labeling must be submitted to the Agency before your product as modified, may be sold or distributed [PR Notice 82-2 and 40 CFR 156.10(a) (6)].

If you have any questions regarding this action, you may contact Mr. Sylvester George at (703) 603-0688 or via e-mail at george.sylvester@epa.gov.

Sincerely,

Linda A. Hollis

Linda A. Hollis, Chief
Biochemical Pesticide Branch
Biopesticides and Pollution
Prevention Division (7511P)

Receipt for Section 3

S: 926813

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Notification

Company: 62097 FINE AGROCHEMICALS, LTD V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team S1

Product #: 62097-27 Product Name: INDOLEBUTYRIC ACID TECHNICAL

Override#

Me Too Section3: Me Too Product Name:

Application Date: 15-Nov-2012  OPP Rec'd Date: 16-Nov-2012 

Front End Date: 16-Nov-2012  Risk Manager Send Date: 16-Nov-2012 

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Product: ☐

Receipt Description:

Notification of additional container sizes.

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

New Product: ☐
Request Date:
New Product: ☐
Received Date:
Signature Date:

Print Letter

Enter More Information

Tracking

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11/16/12
AD

SciReg, Inc.
Science and Regulatory Consultants

November 15, 2012

Ms. Linda Hollis
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Notification Accepted

Date: Nov. 15, 2012

Reviewer: Sylvester George

Re: Indolebutyric Acid Technical (EPA Reg. No. 62097-27)
Additional Container Sizes

Dear Ms. Hollis:

On behalf of Fine Agrochemicals Ltd., SciReg, Inc. is notifying the Agency of additional containers sizes for this product: 1, 5, and 7.5 pounds.

If you have any questions, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

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United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 62097-27	2. EPA Product Manager L. Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Indolebutyric Acid Technical	PM# 91	
5. Name and Address of Applicant (Include ZIP Code) Fine Agrochemicals Ltd. Hill End House Whittington, Worcester WR5 2RQ UK <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	Notification Accepted Date: <u>Nov. 15, 2012</u> Reviewer: <u>Sylvester George</u>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of additional container sizes.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1, 5, and 7.5 lb	5. Location of Label Directions <input checked="" type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.			
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Frederick T. Smith	Title Agent	Telephone No. (Include Area Code) 703/494-6500
Certification I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent (SciReg, Inc.)	
4. Typed Name Frederick T. Smith	5. Date 11/15/12	

Material Sent for Data Extraction

Reg. # 62097-27Description: Indolebutyric Acid Technical☒ Material(s) Sent to Data Extraction Contractors:☐ New Stamped Label Dated _____☒ Notification Dated 10/15/2012 (Accepted)☐ New CSF(s) Dated _____☐ Other: _____☐ Decision #: _____☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Sylvester GeorgePhone: (703) 603-0688 Division: BPPDDate: 10/17/2012



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 17, 2012

SciReg Inc.
12733 Director's Loop
Woodbridge, VA 22192
Attn: Frederick T. Smith

Subject: Notification of additional container sizes consistent with the provisions of PR Notice 98-10.

Product name: Indolebutyric Acid Technical.

EPA Reg. No: 62097-27.

Additional container sizes: 2, 4, 10, 10.5, 15, 20, 25 and 55 pounds.

Your Submission dated October 15, 2012.

Dear Mr. Smith:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 98-10 dated above. A screen of this request has been conducted for its applicability under PRN 98-10, and it has been determined that the action requested falls within the scope of this Notice. Our records have been duly noted, and the application, EPA Form 8750-1 submitted has been stamped "Notification Accepted" and will be placed accordingly in our records.

Three (3) copies of final printed labeling must be submitted to the Agency before your product as modified, may be sold or distributed [PR Notice 82-2 and 40 CFR 156.10(a) (6)].

If you have any questions regarding this action, you may contact Mr. Sylvester George at (703) 603-0688 or via e-mail at george.sylvester@epa.gov.

Sincerely,

Linda A. Hollis

Linda A. Hollis, Chief
Biochemical Pesticide Branch
Biopesticides and Pollution
Prevention Division (7511P)

Receipt for Section 3

S: 325497

Re-submission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Notification

Company: 52097 FINE AGROCHEMICALS, LTD

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 62097-27 Product Name: INDOLEBUTYRIC ACID TECHNICAL

Override:

Me Too

Me Too

Section 3:

Product Name:

Application Date: 15-Oct-2012

OPP Rec'd Date: 15-Oct-2012

Front End Date: 15-Oct-2012

Risk Manager Send Date: 15-Oct-2012

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

NOTIFICATION

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Date

Other

CONTAINER

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:

Rec'd
10/16/12
2013

SciReg, Inc.
Science and Regulatory Consultants

October 15, 2012

Ms. Linda Hollis
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Indolebutyric Acid Technical (EPA Reg. No. 62097-27)
Additional Container Sizes

Dear Ms. Hollis:

On behalf of Fine Agrochemicals Ltd., SciReg, Inc. is notifying the Agency of additional containers sizes for this product: 2, 4, 10, 10.5, 15, 20, 25 and 55 pounds.

If you have any questions, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 62097-27	2. EPA Product Manager L. Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Indolebutyric Acid Technical	PM# 91	
5. Name and Address of Applicant (Include ZIP Code) Fine Agrochemicals Ltd. Hill End House Whittington, Worcester WR5 2RQ UK <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Notification Accepted

Date: 10/17/2012

Reviewer: Sylvester George

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of additional container sizes.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted					
If "Yes" Unit Packaging wgt.		No. Per Container	If "Yes" Package wgt.		No. Per Container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2, 4, 10, 10.5, 15, 20, 25 and 55 lb		5. Location of Label Directions <input checked="" type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application):		
Name Frederick T. Smith	Title Agent	Telephone No. (include Area Code) 703/494-6500
Certification I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		Date Application Received (Stampod)
2. Signature 	3. Title Agent (SciReg, Inc.)	
4. Typed Name Frederick T. Smith	5. Date 10/15/12	

Material Sent for Data Extraction *10/3/12*Reg. # 62097-27Description: IBA Technical☒ Material(s) Sent to Data Extraction Contractors:☐ New Stamped Label Dated _____☒ Notification Dated Sep 24, 2012 (Accepted)☐ New CSF(s) Dated _____☐ Other: _____☐ Decision #: _____☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Sylvester GeorgePhone: (703) 603-0688Division: BPPDDate: 10/3/2012



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 3, 2012

Fine Agro Chemicals, Ltd.
C/O SciReg, Inc.
12733 Director's Loop,
Woodbridge, VA 22192
Attn: Frederick T. Smith

Subject: Notification of additional establishment site per PR Notice 98-10.
Product Name: **Indolebutyric Acid Technical**.
Additional establishment site: **62097- GBR- 001**.
EPA Reg. No: **62097-27**.
Your Submission dated September 24, 2012.

Dear Mr. Smith:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 98-10 dated above. A screen of this request has been conducted for its applicability under PRN 98-10, and it has been determined that the action(s) requested falls within the scope of this Notice. Our records have been duly noted, and the application, (EPA Form 8750-1) submitted has been stamped "Notification Accepted" and will be placed accordingly in our records.

Three (3) copies of final printed labeling must be submitted to the Agency before your product as modified, may be sold or distributed [PR Notice 82-2 and 40 CFR 156.10(a) (6)].

If you have any questions regarding this action, you may contact Mr. Sylvester George at (703) 603-0688 or via e-mail at george.sylvester@epa.gov.

Sincerely,

Linda A. Hollis

Linda A. Hollis, Chief
Biochemical Pesticide Branch
Biopesticides and Pollution
Prevention Division(7511P)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 3, 2012

Fine Agro Chemicals, Ltd.
C/O SciReg, Inc.
12733 Director's Loop,
Woodbridge, VA 22192
Attn: Frederick T. Smith

Subject: Notification of additional establishment site per PR Notice 98-10.
Product Name: **Indolebutyric Acid Technical**.
Additional establishment site: **62097- GBR- 001**.
EPA Reg. No: **62097-27**.
Your Submission dated September 24, 2012.

Dear Mr. Smith:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 98-10 dated above. A screen of this request has been conducted for its applicability under PRN 98-10, and it has been determined that the action(s) requested falls within the scope of this Notice. Our records have been duly noted, and the application, (EPA Form 8750-1) submitted has been stamped "Notification Accepted" and will be placed accordingly in our records.

Three (3) copies of final printed labeling must be submitted to the Agency before your product as modified, may be sold or distributed [PR Notice 82-2 and 40 CFR 156.10(a) (6)].

If you have any questions regarding this action, you may contact Mr. Sylvester George at (703) 603-0688 or via e-mail at george.sylvester@epa.gov.

Sincerely,

Linda A. Hollis

Linda A. Hollis, Chief
Biochemical Pesticide Branch
Biopesticides and Pollution
Prevention Division(7511P)

S: 924283

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Print Letter

Enter More Information

Tracking

Application Type: Notification

Company: 62097 FINE AGROCHEMICALS, LTD

V

Risk Manager: Biologicals & Pollution Prevention Division PM Team 91

Product #: 62097-27

Product Name: INDOLEBUTYRIC ACID TECHNICAL

Override:

Me Too

Section3:

Me Too

Product Name:

Application Date: 24-Sep-2012

id

OPP Rec'd Date: 25-Sep-2012

id

Front End Date: 25-Sep-2012

id

Risk Manager Send Date: 25-Sep-2012

id

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

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Paper Label

View/Edit

Fast Track: ☐New Ingredient: ☐

Receipt Description:

Notification of additional establishments site.

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Rec'd
10-3-12
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SciReg, Inc.
Science and Regulatory Consultants

September 24, 2012

Ms. Linda Hollis
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: IBA Technical (EPA Reg. No. 62097-27)
Additional Establishment Site

Dear Ms. Hollis:

On behalf of Fine Agrochemicals Ltd., SciReg, Inc. is notifying the Agency of an additional establishment for final labeling of IBA Technical, EPA Reg. No. 62097-27. The additional establishment is 62097-GBR-001.

If you have any questions, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

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United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 62097-27	2. EPA Product Manager L. Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) IBA Technical	PM# 91	
5. Name and Address of Applicant (Include ZIP Code) Fine Agrochemicals Ltd. Hill End House Whittington, Worcester WR5 2RQ UK <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>Notification Accepted</u> Product Name <u>Date: Oct 3, 2012</u>	

Section - IIReviewer: Sylvester George

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of additional establishment site.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted			
If "Yes" Unit Packaging wgt.	No. Per Container	If "Yes" Package wgt	No. Per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
		5. Location of Label Directions <input type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Frederick T. Smith	Title Agent	Telephone No. (Include Area Code) 703/494-6500
Certification I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent (SciReg, Inc.)	
4. Typed Name Frederick T. Smith	5. Date 9/24/12	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number:

62097-27

Date of Issuance:

SEP 17 2012

Term of Issuance:

Unconditional

Name of Pesticide Product:

Indolebutyric Acid Technical

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Fine Agrochemicals, Ltd.
Hill End House, Whittington
Worcester, WR5 2RQ
United Kingdom

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his/her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA. This product is unconditionally registered in accordance with FIFRA Sec. 3(c)(5) provided you:

1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Revise the EPA Registration Number to read, "EPA Reg. No. 62097-27".
3. Submit within 1 year after the Date of Registration acceptable data packages for Guideline Studies: Storage Stability study (OPPTS GLN: 830.6317) and Corrosion Characteristics study (OPPTS GLN: 830.6320) for this product.
4. Submit two (2) copies of the final printed labeling before you release the product for shipment.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

[Signature]
Daniel A. Helfgott, Acting Associate Director,
Biopesticides and Pollution Prevention Division

Date:

9/17/12

EPA Form 8570-6

CONCURRENCES

SYMBOL	7511P						
SURNAME	Helfgott						
DATE	9-14-12						

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

29
OFFICIAL FILE COPY

Material to be added to an e-Jacket/Jacket

Reg. No. 62097-27

1. ☒ Placement within the e-Jacket/jacket:

- ☐ Default: (chronological, top/newest)
- ☐ Description: (PDF page number, i.e., "before page 45")

FINAL PRINTED LABEL

2. ☐ Send to Data Extraction contractors this material:

- ☐ Newly stamped accepted label
- ☐ Notification
- ☐ New CSF
- ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's name: Sylvester George

Phone: 603-0688 Division: BPPD

Date: 10/23/2012

Receipt for Section 3

S: 924504

Regubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 62097 FINE AGROCHEMICALS, LTD

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 62097-27 Product Name: INDOLEBUTYRIC ACID TECHNICAL

Overrides:

Me Too

Me Too

Section3:

Product Name:

Application Date: 24-Sep-2012

ie

OPP Rec'd Date: 24-Sep-2012

ie

Front End Date: 24-Sep-2012

ie

Risk Manager Send Date: 24-Sep-2012

ie

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Request 2 copies of the Final Printed Labels for IBA Technical EPA
62097-27

New Ingredient:

Request Date:

New Ingredient:

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

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Other

2 final printed labels f

View/Edit

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10-4-12
AB

SciReg, Inc.
Science and Regulatory Consultants

September 24, 2012

Ms. Linda Hollis
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

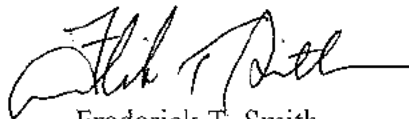
Re: Fine Agrochemicals Ltd.
- IBA Technical (EPA Reg. No. 62097-27)
- Submission of final printed labels

Dear Ms. Hollis:

On behalf of Fine Agrochemicals Ltd. (Fine), SciReg, Inc. is submitting two copies of the final printed label for IBA Technical, in response to the Agency's September 17, 2012 Registration Notice.

If you have any questions, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 62097-27	2. EPA Product Manager L. Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) IBA Technical	PM# 91	
5. Name and Address of Applicant (Include ZIP Code) Fine Agrochemicals Ltd. Hill End House Whittington, Worcester WR5 2RQ UK <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated <u>Sept. 17, 2012</u>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

**Complies with
EPA Accepted Labeling**

Date: Sept 17, 2012

Reviewer: Sebastian George

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. Per Container	If "Yes" Package wgt.	No. Per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Frederick T. Smith		Title Agent		Telephone No. (Include Area Code) 703/494-6500	
Certification I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent (SciReg, Inc.)			
4. Typed Name Frederick T. Smith		5. Date 9/24/12			

INDOLEBUTYRIC ACID TECHNICAL

(FOR MANUFACTURING USE ONLY)

For formulating plant growth regulator products for use on terrestrial food and non-food crops.

Active Ingredient:

Indole-3-butyric Acid 99.7%

Other Ingredients: 0.3%

TOTAL 100.0%

**Complies with
EPA Accepted Label**

Keep Out of Reach of Children

CAUTION

Date: 9/17/2012

Reviewer: Sylvester George

EPA Reg. No.: 62097-27

EPA Est. No.:

NET CONTENTS: 55 lbs. (25 kg)

FIRST AID	
IF SWALLOWED	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything to an unconscious person.
Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu).	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

FOR CHEMICAL EMERGENCY: spill, leak, fire, exposure, or accident call CHEMTREC, 1-800-424-9300.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is to be used only for formulating plant growth regulator products for the following uses:

This product is to be used only for formulating plant growth regulator products for the following uses: vegetable crops, fruit crops, field crops, rice, turfgrass, sod, ornamentals, and seed treatment. This product may also be used to formulate products for any additional uses not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).

Uses for experimental purposes that are in compliance with the US EPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Keep containers tightly closed when not in use.

Pesticide Disposal: Pesticides wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residues into application equipment. Then offer for recycling, if available, or dispose of liner in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

WARRANTY DISCLAIMER AND LIMITATION OF LIABILITY

Fine Agrochemicals Limited ("FINE") warrants that this Product conforms to the specifications on this label. To the extent consistent with applicable law, FINE makes no other warranties and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for a particular purpose. No agent of FINE or any other person is authorized to make any representation or warranty beyond those contained herein.

It is impossible to eliminate all risks associated with this Product. Plant injury, lack of performance, or other unintended consequences may result because of factors such as use of the Product other than in strict accordance with this label's instructions, presence of other materials, the manner of application or other factors, all of which are beyond the control of FINE or the seller. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer.

To the extent consistent with applicable law, FINE disclaims any liability whatsoever for special, incidental or consequential damages resulting from the handling or use of this Product and FINE's liability under this label shall be limited to the amount of the purchase price or, at the election of FINE, the free replacement of the Product.

Fine Agrochemicals Limited
Hill End House, Whittington
Worcester, WR5 2RQ
UNITED KINGDOM

INDOLEBUTYRIC ACID TECHNICAL

(FOR MANUFACTURING USE ONLY)

For formulating plant growth regulator products for use on terrestrial food and non-food crops.

Active Ingredient:

Indole-3-butyric Acid 99.7%

Other Ingredients: 0.3%

TOTAL 100.0%

Keep Out of Reach of Children

CAUTION

EPA Reg. No.: 62097-27

EPA Est. No.:

NET CONTENTS: 55 lbs. (25 kg)

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Uses for experimental purposes that are in compliance with the US EPA requirements.

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**Fine Agrochemicals Limited
Hill End House, Whittington
Worcester, WR5 2RQ
UNITED KINGDOM**

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Other Ingredients: 0.3%

TOTAL..... 100.0%

Keep Out of Reach of Children

CAUTION

ACCEPTED

SEP 17 2012

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 62097-27

EPA Reg. No.: 62097-

EPA Est. No.:

NET CONTENTS: 55 lbs. (25 kg)

FIRST AID	
IF SWALLOWED	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything to an unconscious person.
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To the extent consistent with applicable law, FINE disclaims any liability whatsoever for special, incidental or consequential damages resulting from the handling or use of this Product and FINE's liability under this label shall be limited to the amount of the purchase price or, at the election of FINE, the free replacement of the Product.

Fine Agrochemicals Limited
Hill End House, Whittington
Worcester, WR5 2RQ
UNITED KINGDOM

RE: Indolebutyric Acid Technical (EPA File Symbol No. 62097-ET)
Fred Smith
to:
Colin Walsh
09/05/2012 04:18 PM
Hide Details
From: Fred Smith

To: Colin Walsh/DC/USEPA/US@EPA

Colin—

In response to your email below and our August 27 follow-up telephone discussion, attached please find a revised label and CSF, and the letter Fine sent to Tide last year, for Indolebutyric Acid Technical. See also my comment in your email below.

Please confirm that you received this email and the four attachments.

If you have any questions, please let me know.

Thanks very much.

--Fred

From: Colin Walsh [mailto:Walsh.Colin@epamail.epa.gov]
Sent: Thursday, August 23, 2012 4:43 PM
To: Fred Smith
Subject: Indolebutyric Acid Technical (EPA File Symbol No. 62097-ET)

Hi Fred,

I have completed a review of your package and there a few issues that need to be resolved:

CSF Issue:

1) You must remove the "(99.7)" from box 10 of the CSF for the active ingredient (a.i.).

Labeling Issues:

- 1) In the ingredients statement, you must change the a.i. name to "Indole-3-butyric Acid" to match the name on your CSF.
- 2) As indicated in the Agency's Label Review Manual (LRM), Chapter 7, Section III(F), Table 9, you must change two of the bullet points (#2 and #4) listed for "if swallowed" in your first aid statement to the following:
 - a) "Have person sip a glass of water if able to swallow."
 - b) "Do not give anything to an unconscious person."
- 3) For the contact information for the National Pesticides Information Center (NPIC) in your first aid statement, you must list the hours of operation and website. Refer to the LRM, Chapter 7, Section III(F)(10) for the complete wording that should be used for this section.
- 4) For your Hazards to Humans and Domestic Animals statement, the last sentence must read, "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet." Refer to the LRM, Chapter 7, Section III(D), Table 3 for the appropriate language.
- 5) Remove the last sentence from your Environmental Hazards statement. This is only required for end-use products.

Data Compensation Issues:

1) On your data matrix dated 10/26/2011, you indicate that you are offering to pay to Zhejiang Tide Cropsience; however, on EPA Form 8570-34 dated 09/28/2011, you did not mark the General Offer to Pay box (Section II). You must submit a new EPA Form 8570-34 to the Agency that indicates that you are offering to pay. As we discussed, since we selectively cited data (by MRID No.) and did not use the cite-all option or the selective cite-all option, the General Offer to Pay box on form 8570-34 should not be checked. In addition, you must provide a copy of the offer to pay letter that you sent to Zhejiang Tide Cropsience.

To expedite the review, you may submit the CSF, label, and forms to me directly via email. If you choose to submit the CSF via email, please note that email is not considered by the Agency as a secure form of transmittal of Confidential Business Information. The Agency considers mail a secure form and you may submit the materials via mail if you choose. Please let me know if you have any questions.

Regards,

Colin

Colin G. Walsh, M.S.
 Biologist, Biochemical Pesticides Branch
 Biopesticides and Pollution Prevention Division (7511P)
 Office of Pesticide Programs
 U.S. Environmental Protection Agency
walsh.colin@epa.gov
 (703) 308-0298 (phone)
 (703) 305-0118 (fax)
<http://www.epa.gov/pesticides/>

29 September 2011

Zhejiang Tide Cropscience Co. Ltd
21 Hubble, Irvine, CA 92618

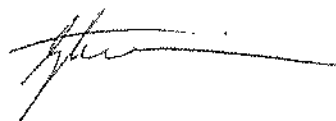
Re: Notice of Intent to Apply for Product Registration

To Whom It May Concern:

According to the current edition of the U.S. Environmental Protection Agency's Pesticide Data Submitters List (March 31, 2011), Zhejiang Tide Cropscience Co. Ltd has submitted data to the Agency to support the registrations of products containing the active ingredient, Indolebutyric Acid.

Pursuant to Title 40, Part 152, Subpart E of the Code of Federal Regulations, this letter is to inform you that Fine Agrochemicals Ltd. intends to submit an application to the EPA for the registration of technical Indolebutyric Acid, and to possibly cite data submitted by you in support of that application. At the appropriate time, and if applicable, an offer to pay compensation will be made in accordance with the Federal Insecticide, Fungicide and Rodenticide Act.

Sincerely,



Maria J McKelvie
Regulatory Specialist
Fine Agrochemicals Limited

FINE AGROCHEMICALS LIMITED
Hill End House, Whittington
Worcester WR5 2RD, UK

T +44 1905 361800
F +44 1905 361810

Indole Butyric Acid
PC Code: 046701
Product Chemistry, Tier I Tox, Tier I Non-targets

DP Number: 396098
EPA Reg. No.: 62097-ET



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

11 June 2012

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Science Review in Support of the Registration of Indole Butyric Acid Technical, Containing 99.7% Indole Butyric Acid (IBA) As Its Active Ingredient. Product Chemistry for the Unregistered Source, Tier I Toxicity Waivers, and Tier I Non-Target Organism Waivers.

Review Type:	Product Chemistry, Tier I Tox, Tier I Non-targets
Decision Number:	455887
DP Number:	396098
EPA File Symbol Number:	62097-ET
Chemical Class:	Biochemical
PC Code:	046701
CAS Number:	133-32-4
Tolerance Exemptions:	40 CFR 180.1099
MRID Numbers:	486109-01 to -07

FROM: Russell S. Jones, Ph.D., Senior Scientist /s/ 06/11/2012
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Colin Walsh, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

On behalf of Fine Agrochemicals, LTD., F. Smith (SciReg) requests registration of Indole Butyric Acid Technical, which is intended for use as a Technical Grade Active Ingredient/Manufacturing Use Product (TGAI/MP). In support of this registration, the registrant has submitted product chemistry studies and data, and rationales to support the data requirements for Tier I Toxicity and Tier I Non-Target Organisms.

RECOMMENDATIONS AND CONCLUSIONS

- 1a. The product chemistry submission is **ACCEPTABLE** pending a minor correction to the CSF, dated 10/26/2011 and submission of data for Stability (OCSPP 830.6313), Storage Stability (OCSPP 830.6317), and Corrosion Characteristics (OCSPP 830.6320). The aforementioned studies are currently in progress.
- 1b. On the CSF, the parenthetical (99.7%) following the name of the active ingredient in Column 10 should be removed. The entire product contains 99.7% a.i.
2. Data and other information submitted in support of the Tier I Toxicity data requirements, in lieu of Guideline studies, are **ACCEPTABLE**. No additional data are required.
3. Data and other information submitted in support of the Tier I Non-Target Organism data requirements, in lieu of Guideline studies, are **ACCEPTABLE**. No additional data are required.

STUDY SUMMARIES

Product Chemistry

Product Identity and Composition (OCSPP 830.1100; MRID 486109-01 & -02): The product is comprised of Indole butyric acid (the active ingredient), and inert ingredient, and minor impurities.

Common Name:	Indolebutyric Acid (IBA)
IUPAC Name:	4-(1H-indol-3-yl) butanoic acid
Synonyms:	Indole-3-butyric Acid, 3-Indolebutyric Acid, 4-(3-Indoyl) butyric acid, 4-(3-Indoyl) butanoic acid,
CAS No.:	133-32-4
PC Code:	046701
Empirical Formula:	C ₁₂ H ₁₃ NO ₂
Molecular Wgt.:	203.24

CLASSIFICATION: ACCEPTABLE

Indole Butyric Acid
PC Code: 046701
Product Chemistry, Tier 1 Tox, Tier 1 Non-targets

DP Number: 396098
EPA Reg. No.: 62097-ET

Description of the Materials Used to Produce the Product, Production Process, and the Formulation Process OCSPP 830.1600; 830.1620; and 830.1650; MRID 48610901): The starting materials are as follows: SEE CONFIDENTIAL APPENDIX

Manufacturing Process: SEE CONFIDENTIAL APPENDIX

CLASSIFICATION: ACCEPTABLE

Discussion of the Formation of Impurities (OCSPP 830.1670; MRID 48610901): SEE CONFIDENTIAL APPENDIX

CLASSIFICATION: ACCEPTABLE

Preliminary Analysis (OCSPP 830.1700; MRID 48610902): SEE CONFIDENTIAL APPENDIX

CLASSIFICATION: ACCEPTABLE

Enforcement Analytical Method (OCSPP 830.1800; MRID 48610902): SEE CONFIDENTIAL APPENDIX

CLASSIFICATION: ACCEPTABLE

Indole Butyric Acid
PC Code: 046701
Product Chemistry, Tier I Tox, Tier I Non-targets

DP Number: 396098
EPA Reg. No.: 62097-ET

Physical and Chemical Properties (OCSP 830.6302 to 830.7950; MRID 47124502):

Table 2. Physical and Chemical Properties for 3-Indolebutyric Acid Technical (EPA File No. 62097-ET)

Guideline (OCSP Number)	Observation	Method
Color (830.6302)	Light Beige	Visual inspection
Physical State (830.6303)	Crystalline Powdery Solid	Visual inspection
Odor (830.6304)	No Odor	-
Stability to Normal/Elevated temps., metals, and metal ions (830.6313)	Study in Progress	-
Oxidation/Reduction: Chemical Incompatibility (830.6314)	In temp. range of 24-26 °C, forms cake upon mixing with water, 5% ammonium phosphate, potassium permanganate, and gasoline; and an inhomogeneous mixture with iron powder. No other changes were observed.	CHBM SOP SHB-OP-MTH-146-P
Flammability (830.6315)	Not Applicable; substance is a non-combustible solid	-
Storage Stability (830.6317)	Study in Progress	-
Miscibility (830.6319)	Not Applicable; substance is not an emulsifiable concentrate	-
Corrosion Characteristics (830.6320)	Study in Progress	-
Dielectric Breakdown Voltage (830.6321)	Not Applicable; substance will not be used around electrical equipment	-
pH (830.7000)	3.54 (1% solution)	pH meter
UV/Visible Light Absorption (830.7050)	Peaks at 221.5 and 280.4 nm in neutral solution; 219.0 and 280.4 nm in acidic solution; and 220.7 and 280.6 nm in basic solution	CHBML-SOP-CHB-OP-MTH-075-P
Viscosity (830.7100)	Not Applicable; substance is a solid	-
Melting Point/Melting Point Range (830.7200)	124.5 °C	Syracuse Research Corporation PhysProp Database
Boiling Point/Boiling Point Range (830.7220)	Not Applicable; substance is a solid	-
Density/Relative Density/Bulk Density (830.7300)	0.602 g/cm ³ (37.6 lbs/cubic foot)	Direct measurement
Particle Size, Fiber Length, and Diameter Distribution (830.7520)	No Applicable; substance is a crystalline powdery solid	-
Partition Coefficient (n-octanol/water) (830.7550; 830.7560; 830.7570)	Log P = 2.30	Syracuse Research Corporation PhysProp Database
Water Solubility: Column elution method; Shake Flask (830.7840)	Water = 250 mg/L Benzene >1000 g/L Acetone, ethanol, diethyl ether = 30-100 g/L Chloroform = 10-100 mg/L	Syracuse Research Corporation PhysProp Database; and the Pesticide Manual, Tenth Edition, 1994 (Editor: Clive Tomlin)
Vapor Pressure (830.7950)	1.17 x 10 ⁻⁴ mm Hg at 25 °C	Syracuse Research Corporation PhysProp Database

CLASSIFICATION: ACCEPTABLE, pending submission of data for Stability (OCSPP 830.6313), Storage Stability (OCSPP 830.6317), and Corrosion Characteristics (OCSPP 830.6320).

Tier I Toxicity

Guideline studies were not submitted. In lieu of studies for acute oral, toxicity, acute dermal toxicity, acute inhalation toxicity, and primary eye irritation, the registrant offered compensation to the data owner, Zhejiang Tide Corporation (CHINA). The study for primary dermal irritation had been previously submitted and reviewed. In lieu of studies for subchronic oral, dermal and inhalation toxicity, mutagenicity, and developmental toxicity, the registrant submitted rationales to support the data requirements.

Table 5. Mammalian Toxicology Data Requirements for

Study/OPPTS Guideline No.	Results	Toxicity Category/Description	MRID
Acute oral toxicity (rat) (870.1100)	LD ₅₀ > 2000 mg/kg ACCEPTABLE	III	47124509
Acute dermal toxicity (rat) (870.1200)	LD ₅₀ > 5050 mg/kg ACCEPTABLE	IV	47124513
Acute inhalation toxicity (rat) (870.1300)	LD ₅₀ > 2.32 mg/L ACCEPTABLE	IV	47124514
Primary eye irritation (rabbit) (870.2400)	No positive effects in any eyes at 24 hrs post-instillation ACCEPTABLE	IV	47124510
Primary dermal irritation (rabbit) (870.2500)	Primary Irritation Score = 0.0415 ACCEPTABLE	Not an Irritant	41863002
Dermal sensitization (guinea pig) (870.2600)	PII = 0 ACCEPTABLE	Not a Sensitizer	42483701
Hypersensitivity incidents (885.3400)	No reports of hypersensitivity ACCEPTABLE	No incidents reported	-
90-Day oral toxicity (870.3100)	Rationale submitted ¹ ACCEPTABLE	Negligible dietary exposure	48644404
90-Day dermal toxicity (870.3250)	Rationale submitted ¹ ACCEPTABLE	No subchronic exposure	48644405
90-Day inhalation toxicity (870.3465)	Rationale submitted ¹ ACCEPTABLE	No subchronic exposure	48644406
Mutagenicity (870.5100, 5300 and 5375)	Studies cited ² ACCEPTABLE	Not a mutagen	40898201 41011401
Developmental toxicity (870.3700)	Rationale submitted ¹ ACCEPTABLE	Negligible exposure	48644407

¹ See IBA Registration Review Final Workplan and Memorandum from G. Casciano to C. Walsh, dated 08/17/2010.

² In vitro mammalian cell assay

Indole Butyric Acid
PC Code: 046701
Product Chemistry, Tier I Tox, Tier I Non-targets

DP Number: 396098
EPA Reg. No.: 62097-ET

Tier I Non-Target Organisms

Guideline studies were not submitted. In lieu of studies, the registrant cited previously reviewed studies and information in support of the data requirements for non-target birds, non-target aquatic organisms, and non-target plants. The active ingredient is considered to be practically non-toxic to birds on an acute and dietary basis, slightly toxic to fish and aquatic invertebrates, and is not expected to be phytotoxic to plants at the rates proposed for use in end-use products (see Memorandum from A. Gonzales to C. Walsh, dated 08/18/2010). A more comprehensive risk assessment was conducted for non-target organisms and endangered species in support of the Registration Review of IBA (see Memorandum from A. Gonzales to Colin Walsh, dated 02/24/2011) which concurred with the Memorandum of 08/18/2010 and additionally determined that IBA is expected to be non-toxic to insects. In addition, an "No Effect" determination was made for threatened and endangered terrestrial and aquatic species.

CLASSIFICATION: ACCEPTABLE

R. S. Jones, C. Walsh, IHAD, BPB/BPPD Subject File
R. S. Jones: F.T. OPY, 703/308-5071: 06/11/2012

Indole Butyric Acid
PC Code: 046701
Product Chemistry, Tier I Tox, Tier I Non-targets

DP Number: 396098
EPA Reg. No.: 62097-ET

CONFIDENTIAL APPENDIX

Manufacturing process information may be entitled to confidential treatment

Indole Butyric Acid
PC Code: 04670I
Product Chemistry, Tier I Tox, Tier I Non-targets

DP Number: 396098
EPA Reg. No.: 62097-ET

Manufacturing process information may be entitled to confidential treatment

DATA PACKAGE BEAN SHEET

Date: 14-Nov-2011

Page 1 of 2

Decision #: 455887

DP #: (396098)

PRIA

Parent DP #:

Submission #: 905966

E-Sub #:

*** Registration Information ***

Registration: 62097-ET - INDOLEBUTYRIC ACID TECHNICAL

Company: 62097 - FINE AGROCHEMICALS, LTD

Risk Manager: RM 91 - Linda Hollis - (703) 308-8733 Room# PY1 S-8761

Risk Manager Reviewer: Colin Walsh CWALSH

Sent Date: 26-Oct-2011

Calculated Due Date: 20-Oct-2012

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (B672) UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;Reduced Fee

Ingredients: 046701, Indole-3-butyric acid(99.7%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 14-Nov-2011

Due Back:

DP Ingredient: 046701, Indole-3-butyric acid

DP Title:

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: BPPD / BPB

Last Possible Science Due Date: 26-Oct-2011

Team Name: RM 91

Science Due Date:

Reviewer Name: Jones, Russell

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Dear Reviewer,

Please review this B672, new MP with an unregistered source of a.i. The data in this data package includes product chemistry (MRIDs 486109-01 thru -02) and rationales for human health toxicity and nontarget organism toxicity (MRIDs 486109-03 and 486444-01 thru -07). Please note that MRIDs 486444-01 thru -07 were submitted in response to the SRT review.

Phase IV due date June 19, 2012.

PRIA due date October 20, 2012.

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
48610901		Smith, F. (2011) Indolebutyric Acid Technical: Product Identity and Composition, Description of Beginning Materials, Description of Manufacturing Process, Discussion of the Formation of Impurities, and Certified Limits. Unpublished study prepared by SciReg, Inc. 41p.	830.1550/Product Identity and composition	Pass (21-Oct-2011)
48610901		Smith, F. (2011) Indolebutyric Acid Technical: Product Identity and Composition, Description of Beginning Materials, Description of Manufacturing Process, Discussion of the Formation of Impurities, and Certified Limits. Unpublished study prepared by SciReg, Inc. 41p.	830.1600/Description of materials used to produce the product	Pass (21-Oct-2011)
48610901		Smith, F. (2011) Indolebutyric Acid Technical: Product Identity and Composition, Description of Beginning Materials, Description of Manufacturing Process, Discussion of the Formation of Impurities, and Certified Limits. Unpublished study prepared by SciReg, Inc. 41p.	830.1620/Description of production process	Pass (21-Oct-2011)
48610901		Smith, F. (2011) Indolebutyric Acid Technical: Product Identity and Composition, Description of Beginning Materials, Description of Manufacturing Process, Discussion of the Formation of Impurities, and Certified Limits. Unpublished study prepared by SciReg, Inc. 41p.	830.1670/Discussion of formation of impurities	Pass (21-Oct-2011)
48610901		Smith, F. (2011) Indolebutyric Acid Technical: Product Identity and Composition, Description of Beginning Materials, Description of Manufacturing Process, Discussion of the Formation of Impurities, and Certified Limits. Unpublished study prepared by SciReg, Inc. 41p.	830.1750/Certified limits	Pass (21-Oct-2011)
48610902		Walker, S. (2011) Analytical Assay Method Validation and Five Batch Characterisation, Impurities Determination by HPLC, Water Content, Sulphated Ash and UV Study for the Effects of Acid and Base for Indolebutyric Acid. Project Number: 1322387. Unpublished study prepared by Intertek ASG. 37p.	830.1700/Preliminary analysis	Pass (21-Oct-2011)
48610902		Walker, S. (2011) Analytical Assay Method Validation and Five Batch Characterisation, Impurities Determination by HPLC, Water Content, Sulphated Ash and UV Study for the Effects of Acid and Base for Indolebutyric Acid. Project Number: 1322387. Unpublished study prepared by Intertek ASG. 37p.	830.1800/Enforcement analytical method	Pass (21-Oct-2011)
48610902		Walker, S. (2011) Analytical Assay Method Validation and Five Batch Characterisation, Impurities Determination by HPLC, Water Content, Sulphated Ash and UV Study for the Effects of Acid and Base for Indolebutyric Acid. Project Number: 1322387. Unpublished study prepared by Intertek ASG. 37p.	830.7050/UV/Visible absorption	Pass (21-Oct-2011)
48610903		Smith, F. (2011) Ecological Effects and Toxicology Waiver Request. Unpublished study prepared by SciReg, Inc. 4p.	850.4100/Terrestrial plant toxicity, Tier 1 (seeding emergence)	Pass (21-Oct-2011)
48610903		Smith, F. (2011) Ecological Effects and Toxicology Waiver Request. Unpublished study prepared by SciReg, Inc. 4p.	850.4150/Terrestrial plant toxicity, Tier 1 (vegetative vigor)	Pass (21-Oct-2011)
48644401		Smith, F. (2011) Waiver Request: Nontarget Plant Toxicity - Seedling Emergence. Unpublished study prepared by SciReg, Inc. 4p.	850.4100/Terrestrial plant toxicity, Tier 1 (seeding emergence)	
48644402		Smith, F. (2011) Waiver Request: Nontarget Plant Toxicity - Vegetative Vigor. Unpublished study prepared by SciReg, Inc. 4p.	850.4150/Terrestrial plant toxicity, Tier 1 (vegetative vigor)	
48644403		Smith, F. (2011) Waiver Request: Nontarget Insect Toxicity. Unpublished study prepared by SciReg, Inc. 4p.	850.4300/Terrestrial plants field study, Tier III	
48644404		Smith, F. (2011) Waiver Request: 90-Day Oral. Unpublished study prepared by SciReg, Inc. 4p.	870.3100/90-Day oral toxicity in rodents	

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
48644405		Smith, F. (2011) Waiver Request: 90-Day Dermal. Unpublished study prepared by SciReg, Inc. 4p.	870.3250/90-day dermal toxicity	
48644406		Smith, F. (2011) Waiver Request: 90-Day Inhalation. Unpublished study prepared by SciReg, Inc. 4p.	870.3465/90-day inhalation toxicity	
48644407		Smith, F. (2011) Waiver Request: Prenatal Developmental Toxicity. Unpublished study prepared by SciReg, Inc. 4p.	870.3700/Prenatal developmental toxicity study	



62097-ET - New PRIA action (B672) with data on your shelf.
Andrew Bryceland to: Colin Walsh

11/03/2011 09:32 AM

Colin,

I placed a new PRIA action on your shelf in the file room. This application went through the SRT and failed (failure letter & checklist in jacket). The registrant has responded to the letter and the response is included with the package on your shelf. I will transfer the jacket to you today. This is a B672 action. This is a manufacturing use product. Please see below for details.

Andy

62097-ET Fine Agrochemicals	Indolebutyric acid technical	Colin Walsh	Decis#: 455887 Subm#: 904287 905966 Code: B672	<p>Coded 10/4/11. Recvd jacket on 10/7/11. Waiting on 86-5. Received data from 86-5 on 10/11/11; MRIDs 486109-01 through -03. Placed in for SRT review (w/ jacket) on 10/11/11. Recvd from SRT on 10/18/11. Failed SRT. Placed SRT failure letter in for signature on w/ Linda on 10/18/11. Received response to SRT letter on 11/3/11. Assigned to Colin on 11/3/11.</p> <p>This is a new manufacturing use product for formulation into other plant growth regulator products. Registrant's response to SRT deficiency letter contained 6 volumes, MRID 486444-01 through -06.</p> <p><u>90 day status meeting: 8/9/12</u></p> <p><u>PRIA Phase Dates:</u> FFS Start Date: 10/20/11 PRIA DUE DATE: 10/20/2012</p> <p>Phase 1: 11/4/11 Phase 2: 12/4/11 Phase 3: 2/4/12 Phase 4: 6/19/12 Phase 5: 10/20/2012</p> <p><u>30 day public comment period:</u></p> <p>This is not a new a.i. This is not a first food, first outdoor, or first residential use for this a.i.</p>
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INDOLEBUTYRIC ACID TECHNICAL

(FOR MANUFACTURING USE ONLY)

For formulating plant growth regulator products for use on terrestrial food and non-food crops.

Active Ingredient:

~~2~~ Indolebutyric Acid.....99.7%

Other Ingredients:.....0.3%

TOTAL.....100.0%

Keep Out of Reach of Children

CAUTION

EPA Reg. No.: 62097-

EPA Est. No.:

NET CONTENTS: 55 lbs. (25 kg)

Batch Code:

FIRST AID	
IF SWALLOWED	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice. <i>sip a glass of water if able to swallow</i>• Have person drink large quantities of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-858-7378 (National Pesticide Information Center) for accidental exposure or emergency medical treatment information. <i>see LAM, Chpt. 7, Section III(F)(10)</i>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, ~~or using tobacco~~ *or using the toilet.*

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your Regional Office of the EPA. ~~Do not contaminate water when disposing of equipment washwaters or rinsate.~~

PHYSICAL OR CHEMICAL HAZARDS

FOR CHEMICAL EMERGENCY: spill, leak, fire, exposure, or accident call CHEMTREC, 1-800-424-9300.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is to be used only for formulating plant growth regulator products for the following uses:

Terrestrial Food Crops:

Barley (cereal grain), beans (black-eyed peas, southern peas, dry, navy, and snap), broccoli, Brussels sprouts, cabbage, cauliflower, citrus fruits, cotton, corn (field, sweet, grain), cucumbers, lettuce, melons, mustard (leafy, stem crop), mustard cabbage (pak choi), oats (cereal grain), onions (bulb, green), peanuts, peas, peppers, potatoes (white, Irish), rice, rye (cereal grain), sorghum, soybeans, spinach, squash (summer, winter, zucchini), strawberries, sugar beets (sugar crop), sugar cane (sugar crop), tomatoes, turnips, wheat (cereal grain).

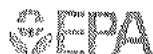
Ornamental herbaceous plants, ornamental woody shrubs and vines, ornamental or shade trees, golf course turf (greens, tees, fairways and rough), ornamental lawns & turf.

Uses for experimental purposes that are in compliance with the US EPA requirements.

STORAGE AND DISPOSAL

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residues into application equipment. Then offer for recycling, if available, or dispose of liner in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

Fine Agrochemicals Limited
Hill End House, Whittington
Worcester, WR5 2RQ
UNITED KINGDOM

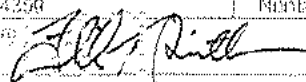


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, CPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 10/26/11	EPA Reg No (File Symbol): 52097-	Page: 1 of 1			
Applicant's/Registrant's Name & Address: Fine Agrochemicals Ltd. Mill End House Whittington, Worcester WR5 2RQ, UK		Product: Indole-3-butyric Acid Technical			
Ingredient: Indole-3-butyric acid					
Guideline Reference Number	Guideline Study Name	MRI# Number	Submitter	Status	Note
830.1550	Product identity and composition		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1600	Desc. of mat. used to produce the product		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1620	Desc. of production process		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1670	Discussion of formation of impurities		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1700	Preliminary analysis		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1750	Certified limits		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1800	Enforcement analytical method		Fine Agrochemicals Ltd.	OWN	Submitted herein
830 series	Physical and chemical properties	47124502	Zhejiang Tide Cropsience	PAY	
830.7050	UV/visible absorption		Fine Agrochemicals Ltd.	OWN	Submitted herein
870.1100 (152-10)	Acute oral toxicity	47124509	Zhejiang Tide Cropsience	PAY	
870.1200 (152-11)	Acute dermal toxicity	47124513	Zhejiang Tide Cropsience	PAY	
870.1300 (152-12)	Acute inhalation toxicity	47124514	Zhejiang Tide Cropsience	PAY	
870.2400 (152-13)	Primary eye irritation	47124510	Zhejiang Tide Cropsience	PAY	
870.2500 (152-14)	Primary dermal irritation	41863002	Synlex	OLD	
870.2600 (152-15)	Dermal sensitization	42463701	Synlex	OLD	
870.3100	90 day oral		Fine Agrochemicals Ltd.	OWN	Submitted herein
870.3250	90 day dermal		Fine Agrochemicals Ltd.	OWN	Submitted herein
870.3465	90 day inhalation		Fine Agrochemicals Ltd.	OWN	Submitted herein
870.3700 (152-23)	Teratogenicity		Fine Agrochemicals Ltd.	OWN	Submitted herein
870.5100	Bacterial irritation			PL	Refer to IBA Summary Document; specific PL referenced by EPA not available.
870.5300	In vitro mammalian cell assay	40898201	Merck	OLD	
		41011451	Merck	OLD	
850.2100 (154-6)	Avian acute oral toxicity	43026701	Indole-3-butyric Acid Task Force	OLD	
		47124505	Zhejiang Tide Cropsience	PAY	
850.2200 (154-7)	Avian dietary toxicity	43026702	Indole-3-butyric Acid Task Force	OLD	
		43026703	Indole-3-butyric Acid Task Force	OLD	
		43026704	Indole-3-butyric Acid Task Force	OLD	
850.1075 (154-01)	Freshwater fish LC50	42090501	BASF Sparks	OLD	
LC50 (1300) (154-9)	Freshwater invertebrate LC50	42090502	BASF Sparks	OLD	
850.4100	Seedling emergence		Fine Agrochemicals Ltd.	OWN	Submitted herein
850.4150	Vegetative vigor		Fine Agrochemicals Ltd.	OWN	Submitted herein
850.4250	Non-target insects		Fine Agrochemicals Ltd.	OWN	Submitted herein
Signature: 			Name and Title: Frederick T. Smith (Agent)		Date: 10/26/11



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0040

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date <u>10/26/11</u>	EPA Reg. No./File Symbol <u>02097-</u>	Page <u>1</u> of <u>1</u>			
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Mill End House Whittington, Worcester WR5 2RQ, UK		Product Indole-3-pyruvic Acid Technical			
Ingredient: Indole-3-pyruvic acid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	DWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Zhejiang Tide Crop Science	PAY	
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Zhejiang Tide Crop Science	PAY	
			Zhejiang Tide Crop Science	PAY	
			Zhejiang Tide Crop Science	PAY	
			Zhejiang Tide Crop Science	PAY	
			Syntex	OLD	
			Syntex	OLD	
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
				PL	Refer to dBA Summary Document; specific PL referenced by EPA not available
			Merck	OLD	
			Merck	OLD	
			Indole-3-pyruvic Acid Task Force	OLD	
			Zhejiang Tide Crop Science	PAY	
			Indole-3-pyruvic Acid Task Force	OLD	
			Indole-3-pyruvic Acid Task Force	OLD	
			Indole-3-pyruvic Acid Task Force	OLD	
			BASF Sparks	OLD	
			BASF Sparks	OLD	
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
Signature: <u>Fredrick T. Smith</u>	Name and Title Fredrick T. Smith (Agent)		Date 10/26/11		

BPPD New Product/Non-Registered AI Source Readiness Screen

Date: 10/17/2011

Review Date: 10/13/2011

File Symbol No.: 62097-ET

Reviewers: John Fournier, Gina Casciano

BPB/MPB: BPB

Comments: The applicant requests to fulfill the requirements for 90-day oral, 90-day dermal, 90-day inhalation, prenatal development, non-target plant toxicity, and non-target insect toxicity with rationale from the Agency's 1992 RED on IBA. The Agency RED is no longer sufficient to address these requirements due to recent Agency review of IBA data in the Registration Review program. The applicant should use the rationale present in the IBA Registration Review Final work plan (which references the PWP and Agency Memo dated 8/17/2010), all appearing in docket EPA-HQ-OPP-2010-0608, at www.regulations.gov. The applicant MUST address each data requirement individually and not in one lump explanation, and not by simply citing the FWP document (since this is not a Final Decision Document). Rather, use the rationale and references included in the FWP document to make your case. Note: If any of the data or rationale in the FWP are from another registrant, this applicant will need to check to see if anything is compensable or exclusive use.

Pass/Fail: FAIL

Hours Worked: 2.0

	Checklist Item	Yes	No	N/A	Comments
1.	Forms				
a.	8570-1: Application for Registration	X			
b.	8570-4: CSF	X			
c.	8570-27: Formulator's Exemption			X	
d.	8570-34: Certification with Respect to Data	X			
e.	8570-35: Data Matrix	X			
2.	Confidential Statement of Formula (CSF)-review for alternate formulations too				
a.	Signed and dated	X			
b.	Food-use? (If no, skip to 1e.)	X			
c.	All inerts cleared for food-use			X	No inert ingredients – impurities only.
d.	Active cleared for food-use	X			
e.	All inerts cleared for nonfood-use (skip if food-use)				

f.	Conventional or antimicrobial actives present?		X		
g.	CSF accurately reflects label	X			
h.	Active(s) + Inert(s) = 100%	X			
i.	CAS #s for all inerts	X			
j.	Chemical names provided for inerts	X			
k.	Units in all applicable boxes		X		pH must be listed on the CSF.
l.	Proprietary inerts? If so, is info. on file with the Agency?		X		
m.	Supplier information adequately listed	X			
n.	Certified limits correct?	X			
o.	If certified limits are outside recommended range, explanation provided?			X	
p.	Microbial: culture collection reference			X	
q.	Microbial: strain designation for a.i.			X	
r.	Microbial: potency provided with a.i.			X	
s.	Alternate formulations?		X		
t.	Are alternate formulations actually alternate and not a new product?			X	
3.	Data Matrix-ACTIVE INGREDIENT				
a.	Separate data matrix for the source of AI		X		
b.	All product chemistry data requirements addressed (guideline by guideline)		X		Physical and Chemical Characteristics not listed guideline by guideline, cited in lump from MRID 47124502.
c.	All toxicology data requirements addressed (guideline by guideline)	X			
d.	All nontarget toxicology data requirements addressed (guideline by guideline)		X		Non-target Insect testing data requirement is not listed on the data matrix; applicant must list this requirement .
e.	Reflects info. reported on CSF (e.g.: identity of AI)	X			
Note for 3b.-d. above: if not addressed in data matrix, may be addressed in elsewhere in submission					
4.	Data Matrix-MP or EP				
a.	Separate data matrix for the product		X		The MP consists only of the TGA. Additional data set is not required.

b.	All product chemistry/product analysis data requirements addressed (guideline by guideline)			X	
c.	All mammalian/human health toxicology/ pathogenicity data requirements addressed (guideline by guideline)			X	
d.	All Tier 1 nontarget organism toxicology/ pathogenicity data requirements addressed (guideline by guideline)			X	
e.	Efficacy data (if public health pests on label)			X	
f.	HSRB review required?		X		
5.	Data Requirements-Guideline Studies				
	Note: This section is for submitted guideline studies only. See below for waivers and rationales.				
a.	Product chemistry: do all submitted studies appear to satisfy the data requirements?				
b.	Toxicology: do all submitted studies appear to satisfy the data requirements?				
c.	Nontargets: do all the submitted studies appear to satisfy the data requirements?				
d.	Other (residue data, special studies, etc.)				
6.	Data Requirements- Waivers				
	Note: This section is for waivers only. This does not apply to rationale submitted to satisfy the data requirements.				
a.	Are there any requests for waivers? Please note.		X		What the applicant refers to as waiver requests are statements of scientific rationale based on the Agency's 1992 RED for IBA. (see Section 7., below).
b.	For each applicable data requirement, does the waiver request have a separate scientific rationale justifying why testing is not applicable?			X	
c.	Does each waiver request seem reasonable and justified?			X	
7.	Data Requirements- Rationales/Literature				
	Note: This section is for rationales only. This does not apply to requests submitted to waive the data requirements.				

a.	Have rationales been submitted in lieu of guideline studies? Please note.	X			The applicant requests to fulfill the requirements for 90-day oral, 90-day dermal, 90-inhalation, prenatal development, non-target plant toxicity, and non-target insect toxicity with rationale from the Agency's 1992 RED on IBA.
b..	Does each rationale have scientific literature citations where applicable?			X	Agency RED.
c.	Are the rationale and scientific citations organized in reasonable order to facilitate timely review and is each guideline addressed individually?	X			
d.	Are copies of cited scientific literature included in the package?			X	Agency RED.
e.	Does the rationale appear to be reasonable and scientific?		X		The Agency RED is not sufficient to address these requirements. The applicant must use the rationale present the IBA Final work plan (which references the PWP and Agency Memo dated 8/17/2010).
8. Label					
a.	Restricted Use Pesticide statement (If applicable)			X	
b.	Product name, brand or trademark	X			
c.	Ingredient statement correct? Microbial: strain designation Microbial: potency designation	X			
d.	"Keep Out of Reach of Children" (KOOROC) Statement	X			
e.	Signal word	X			
f.	First aid statement	X			
g.	Net contents/net weight	X			
h.	EPA Reg. No. and Establishment No.	X			
i.	Company name and address	X			
j.	Precautionary statement: hazards to human and domestic animals Microbial: dusk mask statement	X			

k.	Environmental hazards	X			
l.	Physical and chemical hazards (if app.)	X			
m.	Directions for use	X			
m.	Storage and disposal	X			
o.	Warranty statement	X			
p.	Worker protection			X	
q.	Batch code		X		Label must contain a batch code.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 06, 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SCIREG, INC.
FINE AGROCHEMICALS, LTD
12733 DIRECTOR'S LOOP
WOODBIDGE, VA 22192

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 29-SEP-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 804287
 Regulatory Type: Product Registration - Section 3
 Application Type: New Registration
 Company: 62097 FINE AGROCHEMICALS, LTD
 Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91
 Product #: 62097-ET Product Name: INDOLEBUTYRIC ACID TECHNICAL
 Me Too Section 3: Me Too Product Name:
 Application Date: 29-Sep-2011
 Front End Date: 29-Sep-2011
 FFS Due Date:
 OPP Target Date:
 Fee For Service: Yes
 Billable: Yes

Print Letter
 Enter More Information
 Tracking

OPP Rec'd Date: 29-Sep-2011
 Risk Manager Send Date:
 Negotiated Due Date:
 Fast Track: New Ingredient:

Receipt Content
 Study
 CSF

Receipt Description:

New registration application

New Ingredient Request Date:
 New Ingredient Received Date:
 Signature Date:

Form A: Signature Date:

Form B: Signature Date:

Decos# 455887

B672 (12 months)

FFS start: 10/20/11

PRIA due date: 10/20/12

Phase 1: 11/4/11

Phase 2: 12/4/11

Phase 3: 2/4/12

Phase 4: 6/19/12

Phase 5: 10/20/12

SciReg, Inc.
Science and Regulatory Consultants

48610900

September 29, 2011

Ms. Linda Hollis
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: New Product Registration Application
- Indolebutyric Acid Technical

Dear Ms. Hollis:

On behalf of Fine Agrochemicals Ltd., SciReg, Inc. is submitting a new product registration application for Indolebutyric Acid Technical. In support of this application, Fine is submitting product-specific Group A product chemistry, UV/visible absorption data, various waiver requests, and is relying on the selective citation method of support for all other data requirements.

This regulatory action falls under PRIA Category B672. The PRIA payment receipt is enclosed.

If you have any questions regarding the application materials, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

TRANSMITTAL DOCUMENT

Submitter

Fine Agrochemicals Ltd.
Hill End House
Whittington
Worcester WR5 2RQ
United Kingdom

SciReg, Inc.*
12733 Director's Loop
Woodbridge, VA 22192

*SciReg, Inc. is the authorized agent for Fine Agrochemicals Ltd.

Regulatory action in support of which this package is submitted

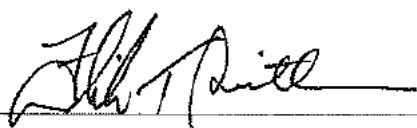
Product Registration:
Indolebutyric Acid Technical

Transmittal Date

September 28, 2011

Contents

	Volume 1	Administrative Materials
48610901	Volume 2	Product Identity and Composition, Description of Beginning Materials, Description of Production Process, Discussion of the Formation of Impurities, and Certified Limits (OPPTS 830.1550, 830.1600, 830.1620, 830.1670, and 830.1750)
48610902	Volume 3	Preliminary Analysis, Analytical Method, and UV/Visible Adsorption (OPPTS 830.1700, 830.1800, and 830.7050)
48610903	Volume 4	Toxicology and Ecological Effects Waiver Requests (OPPTS 850.4100, 850.4150, 850.4350, 870.3100, 870.3250, 870.3465, 870.3700)

Company Official: Frederick T. Smith 
Company Name: SciReg, Inc.
Company Contact: Frederick T. Smith (703) 494-6500



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 31, 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SCIREG, INC.
FINE AGROCHEMICALS, LTD
12733 DIRECTOR'S LOOP
WOODBIDGE, VA 22192

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 26-OCT-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 905966

Resubmission: ☒ Yes ☐ No

Regulatory Type: Product Registration Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: New Registration

Billable: ☐ Yes ☒ No

Company: 62097 FINE AGROCHEMICALS, LTD

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 62097-ET Product Name: INDOLEBUTYRIC ACID TECHNICAL

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 26-Oct-2011



OPP Rec'd Date: 26-Oct-2011



Front End Date: 26-Oct-2011



Risk Manager Send Date: 26-Oct-2011



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

response to EPA letter of 10/19/11

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

Rec'd
6/13/11
AM

SciReg, Inc.
Science and Regulatory Consultants

48644400

October 26, 2011

Ms. Linda Hollis
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Response to EPA letter dated, October 19, 2011
- Indolebutyric Acid Technical (File Symbol 62097-ET)

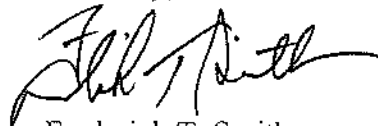
Dear Ms. Hollis:

On behalf of Fine Agrochemicals Ltd., SciReg, Inc. is responding to the Agency's October 19, 2011 deficiency letter concerning Indolebutyric Acid Technical (File Symbol 62097-ET). Attached please find the following:

- Revised Confidential Statement of Formula
- Revised data matrix (public and file copies)
- Revised label (5 copies)
- Individual waiver requests for toxicology and ecological effects data requirements

If you have any questions regarding the application materials, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

TRANSMITTAL DOCUMENT

Submitter

Fine Agrochemicals Ltd.
Hill End House
Whittington
Worcester WR5 2RQ
United Kingdom

SciReg. Inc.*
12733 Director's Loop
Woodbridge, VA 22192

*SciReg. Inc. is the authorized agent for Fine Agrochemicals Ltd.

Regulatory action in support of which this package is submitted

Product Registration:
Indolebutyric Acid Technical (File Symbol 62097-ET)

Transmittal Date

October 26, 2011

Contents

Volume 1	Administrative Materials
48644401 Volume 2	Nontarget plant toxicity – seedling emergence Waiver Request (OPPTS 850.4100)
48644402 Volume 3	Nontarget plant toxicity – vegetative vigor Waiver Request (OPPTS 850.4150)
48644403 Volume 4	Nontarget insect toxicity Waiver Request (OPPTS 850.4350)
48644404 Volume 5	90-day oral Waiver Request (OPPTS 870.3100)
48644405 Volume 6	90-day dermal Waiver Request (OPPTS 870.3250)
48644406 Volume 7	90-day inhalation Waiver Request (OPPTS 870.3465)
48644407 Volume 8	Prenatal developmental toxicity (OPPTS 870.3700)

Company Official: Frederick T. Smith 


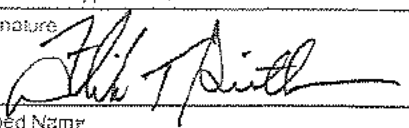
Company Name: SciReg, Inc.

Company Contact: Frederick T. Smith (703) 494-6500

Administrative Materials

[illegible]

73

 <p>United States Environmental Protection Agency Washington, DC 20460</p>		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 62097-ET		2. EPA Product Manager L. Hollis	
4. Company/Product (Name) Indolebutyric Acid Technical		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (include ZIP Code) Fine Agrochemicals Ltd. Hill End House, Whittington Worcester, WR5 2RQ, UK <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section - II			
<input type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>Oct. 19, 2011</u>		<input type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.)			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted			
3. Location of Net Contents Information: <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
5. Location of Label Directions <input type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Frederick T. Smith		Title Agent	
		Telephone No. (Include Area Code) 703/494-6500	
Certification I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			5. Date Application Received (Stamped)
2. Signature 		3. Title Agent (SciReg, Inc.)	
4. Typed Name Frederick T. Smith		5. Date 10/26/11	

SciReg, Inc.
Science and Regulatory Consultants

48644400

October 26, 2011

Ms. Linda Hollis
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Response to EPA letter dated, October 19, 2011
- Indolebutyric Acid Technical (File Symbol 62097-ET)

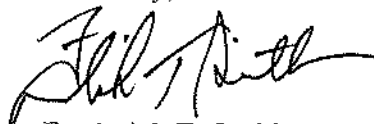
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- Revised Confidential Statement of Formula
- Revised data matrix (public and file copies)
- Revised label (5 copies)
- Individual waiver requests for toxicology and ecological effects data requirements

If you have any questions regarding the application materials, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

TRANSMITTAL DOCUMENT

Submitter

Fine Agrochemicals Ltd.
Hill End House
Whittington
Worcester WR5 2RQ
United Kingdom

SciReg. Inc.*
12733 Director's Loop
Woodbridge, VA 22192

*SciReg. Inc. is the authorized agent for Fine Agrochemicals Ltd.

Regulatory action in support of which this package is submitted

Product Registration:
Indolebutyric Acid Technical (File Symbol 62097-ET)

Transmittal Date

October 26, 2011

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48644407 Volume 8	Prenatal developmental toxicity (OPPTS 870.3700)

Company Official: Frederick T. Smith 

Company Name: SciReg. Inc.

Company Contact: Frederick T. Smith (703) 494-6500

SciReg, Inc.
Science and Regulatory Consultants

48610900

September 29, 2011

Ms. Linda Hollis
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: New Product Registration Application
- Indolebutyric Acid Technical

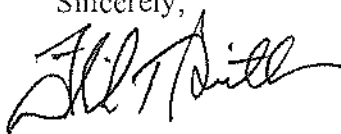
Dear Ms. Hollis:

On behalf of Fine Agrochemicals Ltd., SciReg, Inc. is submitting a new product registration application for Indolebutyric Acid Technical. In support of this application, Fine is submitting product-specific Group A product chemistry, UV/visible absorption data, various waiver requests, and is relying on the selective citation method of support for all other data requirements.

This regulatory action falls under PRIA Category B672. The PRIA payment receipt is enclosed.

If you have any questions regarding the application materials, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

TRANSMITTAL DOCUMENT

Submitter

Fine Agrochemicals Ltd.
Hill End House
Whittington
Worcester WR5 2RQ
United Kingdom

SciReg, Inc.*
12733 Director's Loop
Woodbridge, VA 22192

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Regulatory action in support of which this package is submitted

Product Registration:
Indolebutyric Acid Technical

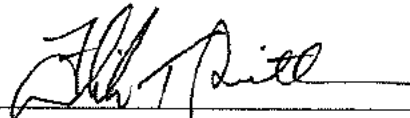
Transmittal Date

September 28, 2011

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48610902	Volume 3	Preliminary Analysis, Analytical Method, and UV/Visible Adsorption (OPPTS 830.1700, 830.1800, and 830.7050)
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Company Official: Frederick T. Smith



Company Name: SciReg, Inc.

Company Contact: Frederick T. Smith (703) 494-6500



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 20, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-455887
EPA File Symbol or Registration Number: 62097-ET
Product Name: INDOLEBUTYRIC ACID TECHNICAL
EPA Application Receipt Date: 29-Sep-2011
EPA Waiver Request Receipt Date: 29-Sep-2011
EPA Company Number: 62097
Company Name: FINE AGROCHEMICALS, LTD

JAMES DAMICO
SCIREG, INC.
FINE AGROCHEMICALS, LTD
12733 DIRECTOR'S LOOP
WOODBIDGE, VA 22192-

SUBJECT: Approval of 50% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has approved your request for 50% waiver of the pesticide registration fee associated with the action referenced above. The decision review period for this action will begin on the date of this letter.

The Action has been identified as Action Code: B672

UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;Reduced Fee:
Linked to PRIA Application;TIER I DATA REQUIREMENTS FOR PRODUCT CHEMISTRY,
TOXICOLOGY, NON-TARGET ORGANISMS & PRODUCT PERFORMANCE MUST BE
ADDRESSED WITH PRODUCT-SPECIFIC DATA OR REQUESTS FOR DATA WAIVERS
WITH SUPPORTING SCIENCE;NO DATA COMPENSATION ISSUES;NON-FOOD USE
OR FOOD USE HAVING ESTABLISHED TOLERANCE OR TOLERANCE EXEMPTION;

If you have any questions, please contact Mr. Robert Forrest, at (703) 308-9376.

Sincerely,

A handwritten signature in black ink, appearing to read "Oscar Morales".

Oscar Morales, Director
Information Technology & Resources Management Division
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OCT 19 2011

OFFICE OF
Chemical Safety and
TOXIC SUBSTANCES

Mr. Frederick T. Smith
Authorized Representative for Fine Agrochemicals, Ltd.
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

RE: **Product Name: Indolebutyric Acid Technical**
EPA File Symbol: 62097-ET
Decision No.: 455887
Application dated: September 28, 2011
EPA Pin-punch date September 29, 2011
PRIA Category: B672
Fee Status: Paid

Dear Mr. Smith:

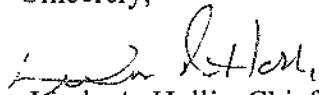
The application referred to above, submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended, and the Pesticide Registration Improvement Act (PRIA) has been given a detailed preliminary screen completeness by the Submission Readiness Team (SRT) of the Biopesticides and Pollution Prevention Division (BPPD) to ensure that this PRIA application/submission is ready for EPA review. This process has been developed to improve the quality of submission packages received by BPPD and aid in our effort to reduce the number of renegotiations and increase the timeliness in which BPPD responds when deficiencies are found.

Your submission has failed the screen for completeness and is therefore considered not reviewable at this time. Please see the Confidential Appendix attached for the reasons for incompleteness.

The subject application (PRIA Category Code **B 672**) has a decision due date of October 20, 2012. At this time, the application is considered incomplete and not reviewable until you address all of the deficiencies identified in this letter. Per 40 CFR 152.105, your application will be administratively withdrawn without further notice to you if you do not submit the missing information within 75 days (**JAN - 3 2012**) from

the date of this letter. It is strongly advised that the deficiencies are adequately addressed prior to the 75 day date above. Submission of the above information by or on the 75 day due date will cause the Agency to renegotiate the PRIA due date so that the full time is allotted.

Sincerely,

A handwritten signature in dark ink, appearing to read "Linda A. Hollis", is written over the printed name.

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
7511P

~~CONFIDENTIAL APPENDIX~~

Confidential Statement of Formula (CSF)

- pH must be listed on the CSF.

Data Requirements-Guideline Studies

You have requested to fulfill the requirements for 90-day oral, 90-day dermal, 90-day inhalation, prenatal development, non-target plant toxicity, and non-target insect toxicity with rationale from the Agency's 1992 RED on Indole Butyric Acid (IBA). The Agency RED is no longer sufficient to address these requirements due to recent Agency review of IBA data in the Registration Review program. You should use the rationale present in the IBA Registration Review Final work plan (FWP) (which references the Preliminary Work Plan (PWP) and the Agency Memo dated 8/17/2010), all appearing in docket EPA-HQ-OPP-2010-0608, at www.regulations.gov. You MUST address each data requirement individually and not in one lump explanation, and not by simply citing the FWP document (since this is not a Final Decision Document). Rather, use the rationale and references included in the FWP document to make your case. Also please note that if any of the data or rationale in the FWP are from another registrant, you will need to check to see if anything is compensable or exclusive use.

Toxicology

- You requested to fulfill the requirements for 90-day oral, 90-day dermal, 90-day inhalation, and prenatal development with rationale from the Agency's 1992 RED on IBA. As indicated above the Agency RED is not sufficient to address these requirements.

Non-targets

- You requested to fulfill the requirements for non-target plant toxicity and non-target insect toxicity with rationale from the Agency's 1992 RED on IBA. As indicated above the Agency RED is not sufficient to address these requirements.

Label

- Batch code is needed on the product label

Data Matrix

- Non-target Insect testing data requirement is not listed on the data matrix; you must list this requirement.

21-Day Screen Completed by
Contractor

21-Day Expires on 10-20-11

Jacket # 62097-ET
MRID# 486109

Content Screen: Recommend to Pass/Fail

86-5 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

ANDREW BRYCELAND

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 9-29-11 ^{3/23/09}

Experts In-Processing Signature: B. R. Date 10-5-11 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>62097-ET</u>		EPA Receipt Date: <u>9-29-11</u>							
Items for Review			Yes	No	N/A*				
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type		X						
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)		X						
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> </table>	yes	no					
yes	no								
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)		X						
	Certificate and data matrix consistent		X						
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> </table>	yes	no					
yes	no								
	If applicable, is there a letter of Authorization for exclusive use only.								
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)				X				
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)		X						
	a) Selective Method (Fee category experts use)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td style="text-align: center; padding: 2px;">X</td> <td></td> </tr> </table>	yes	no	X				
yes	no								
X									
b) Cite-All (Fee category experts use)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> </table>	yes	no						
yes	no								
c) Applicant owns all data (Fee category experts use)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: center; padding: 2px;">yes</th> <th style="text-align: center; padding: 2px;">no</th> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> </table>	yes	no						
yes	no								
6	5 Copies of Label (link to http://www.epa.gov/oppead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)		X						

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- No inerts to review, Technical and impurities only.
- Contacted registrant 10/06/11 for:
Study 02 (Volume 03) page 16 → illegible. (*see attached email)
- ↳ On 10/06/11 registrant sent revised page.
- Studies passed 86-5 Review.

JB

10/06/11

MRID: 486109

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/opbpbpd1/biopesticides/contacts_bpdpd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Frederick Smith
Phone #: 703-494-6500
Email: fsmith@scireg.com

First Call/Initials:

Date: 10/06
Time:

Second Call/Initials:

Date:
Time:

This is _____, EPA contractor.

I'm calling regarding your submission in support of
Indolebutyric Acid Technical 62097-ET.

We have found the following deficiencies regarding:

PR Notice 86.5: Yes or No

Volume/Study Title: 02 (vol 03)

✓ FR (pg. 16) Analytical Assay Method validation ...

Volume/Study Title:

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No

These deficiencies have been approved by EPA.

The corrections can be faxed to 703-305-5060/Attn: _____.

Second Call/Email:

If we do not receive the corrections by _____, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.



RE: EPA Submission: Indolebutyric Acid Technical (EPA Registration Number: 62097-ET)

Fred Smith to: Jennifer Brandon
Cc: Sree Nair

10/06/2011 02:27 PM

Dear Ms. Brandon--

Attached is a copy of page 16 marked "Best Available Copy." If you have any further questions, please let me know.

Kind regards,

Fred

Frederick T. Smith
Senior Regulatory Specialist
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192
USA
Phone: (703) 494-6500
Fax: (703) 492-6600
www.SciReg.com

-----Original Message-----

From: Brandon.Jennifer@epamail.epa.gov [mailto:Brandon.Jennifer@epamail.epa.gov]
Sent: Thursday, October 06, 2011 1:39 PM
To: Fred Smith
Cc: Nair.Sree@epamail.epa.gov
Subject: EPA Submission: Indolebutyric Acid Technical (EPA Registration Number: 62097-ET)

Mr. Smith,

This is a follow-up email with regard to your submission Indolebutyric Acid Technical (EPA Registration Number: 62097-ET). We have found the following deficiencies:

-Study 02: (Volume 03)

Analytical Assay Method Validation and Five Batch Characterization, Impurities Determination by HPLC, Water Content, Sulphated Ash and UV Study for the Effects of Acid and Base for Indolebutyric Acid. Study Number: 1322387

Page 16 in this study is illegible (Figure 1). If this is the "best available copy" on record, please indicate so on the illegible page.

You can send the revised page either by fax to 703-305-5060/ ATTN: Jennifer Brandon or email them to brandon.jennifer@epa.gov.

If you have any questions or require additional information, please do not hesitate to contact me.

Thanks,

Jennifer Brandon
Data Analyst (EPA Contractor)
2777 S. Crystal Drive

Arlington, VA 22202
Ph: 703-305-0074
Fax: 703-305-5060
Email: brandon.jennifer@epa.gov



62097-ET, p 16, Vol 3, 10-6-11.pdf



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 4, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-455887
EPA File Symbol or Registration Number: 62097-ET
Product Name: INDOLEBUTYRIC ACID TECHNICAL
EPA Receipt Date: 29-Sep-2011
EPA Company Number: 62097
Company Name: FINE AGROCHEMICALS, LTD

JAMES DAMICO
SCIREG, INC.
FINE AGROCHEMICALS, LTD
12733 DIRECTOR'S LOOP
WOODBIDGE, VA 22192-

SUBJECT: Receipt of Application and 50% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 50% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

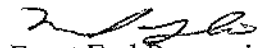
The Action has been identified as Action Code: B672

UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;Reduced Fee:
Linked to PRIA Application;TIER I DATA REQUIREMENTS FOR PRODUCT CHEMISTRY,
TOXICOLOGY, NON-TARGET ORGANISMS & PRODUCT PERFORMANCE MUST BE
ADDRESSED WITH PRODUCT-SPECIFIC DATA OR REQUESTS FOR DATA WAIVERS
WITH SUPPORTING SCIENCE;NO DATA COMPENSATION ISSUES;NON-FOOD USE
OR FOOD USE HAVING ESTABLISHED TOLERANCE OR TOLERANCE EXEMPTION;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 305-7973.

Sincerely,

A handwritten signature in black ink, appearing to be "R. J. [unclear]".

Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service

my
{904287C~

This package includes the following

- ☒ New Registration
- ☐ Amendment

- ☒ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☒ BPPD
- ☐ RD

Risk Mgr. 91

Receipt No.

S- 904287

EPA File Symbol/Reg. No.

62097-ET

Pin-Punch Date:

9/29/2011

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted: B672

Amount Due: \$ _____

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Andrew Bryceand

Date: 10/4/11

Remarks:

Receipt for Section 3

S 904287

Reimbursement: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 62097 FINE AGROCHEMICALS, LTD V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 62097-ET Product Name: INDOLEBUTYRIC ACID TECHNICAL

Overhead:

Me Too Section3: Me Too Product Name:

Application Date: 29-Sep-2011  OPP Rec'd Date: 29-Sep-2011 

Front End Date: 29-Sep-2011  Risk Manager Send Date: 

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

New registration application

New Ingredient
Review Date:
New Ingredient
Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study
CSF
< >

View/Edit

Fred Smith

Subject: Pay.Gov Payment Confirmation

From: paygovadmin@mail.doc.twai.gov [mailto:paygovadmin@mail.doc.twai.gov]

Sent: 14 September 2011 15:26

To: Kelly Gardiner

Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Transaction Summary

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 254EDU2A

Agency Tracking ID: 74237540427

Transaction Type: Sale

Transaction Date: Sep 14, 2011 10:26:09 AM

Account Holder Name: k gardiner

Transaction Amount: \$4,134.50

Billing Address: fine agrochemicals ltd

Billing Address 2: hill end house

City: worcester

State/Province: worcestershire

Zip/Postal Code: WR52RQ

Country: GBR

Card Type: Visa


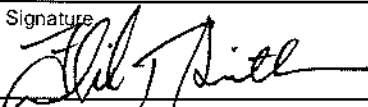
Decision Number:

Registration Number: 62097

Company Name: Fine Agrochemicals Ltd

Company Number: 00441905361800

Action Code: B672

 <div style="margin-left: 100px;"> United States Environmental Protection Agency Washington, DC 20460 </div>		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 62097- <u>ET</u>		2. EPA Product Manager L. Hollis	
4. Company/Product (Name) Indolebutyric Acid Technical		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Fine Agrochemicals Ltd. Hill End House, Whittington Worcester, WR5 2RQ, UK <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section - II			
<input type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.		<input checked="" type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Initial application to register. PRIA Category: B672 PRIA Fee: \$8,269 (\$4,134.50 after 50% reduction) Contact: fsmith@scireg.com			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted			
If "Yes" Unit Packaging wgt. No. Per Container		If "Yes" Package wgt. No. Per Container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 25 kg	
		5. Location of Label Directions <input checked="" type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Frederick T. Smith		Title Agent	
		Telephone No. (Include Area Code) 703/494-6500	
Certification I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent (SciReg, Inc)	
4. Typed Name Frederick T. Smith		5. Date 9/28/11	

SciReg, Inc.
Science and Regulatory Consultants

September 29, 2011

Ms. Linda Hollis
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: New Product Registration Application
- Indolebutyric Acid Technical

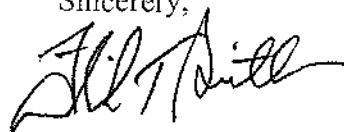
Dear Ms. Hollis:

On behalf of Fine Agrochemicals Ltd., SciReg, Inc. is submitting a new product registration application for Indolebutyric Acid Technical. In support of this application, Fine is submitting product-specific Group A product chemistry, UV/visible absorption data, various waiver requests, and is relying on the selective citation method of support for all other data requirements.

This regulatory action falls under PRIA Category B672. The PRIA payment receipt is enclosed.

If you have any questions regarding the application materials, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

TRANSMITTAL DOCUMENT

Submitter

Fine Agrochemicals Ltd.
Hill End House
Whittington
Worcester WR5 2RQ
United Kingdom

SciReg, Inc.*
12733 Director's Loop
Woodbridge, VA 22192

*SciReg, Inc. is the authorized agent for Fine Agrochemicals Ltd.

Regulatory action in support of which this package is submitted

Product Registration:
Indolebutyric Acid Technical

Transmittal Date

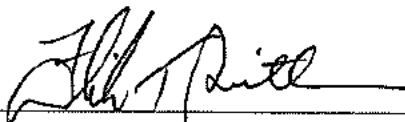
September 28, 2011

Contents

Volume 1	Administrative Materials
Volume 2	Product Identity and Composition, Description of Beginning Materials, Description of Production Process, Discussion of the Formation of Impurities, and Certified Limits (OPPTS 830.1550, 830.1600, 830.1620, 830.1670, and 830.1750)
Volume 3	Preliminary Analysis, Analytical Method, and UV/Visible Adsorption (OPPTS 830.1700, 830.1800, and 830.7050)
Volume 4	Toxicology and Ecological Effects Waiver Requests (OPPTS 850.4100, 850.4150, 850.4350, 870.3100, 870.3250, 870.3465, 870.3700)

Company Official:

Frederick T. Smith



Company Name:

SciReg, Inc.

Company Contact:

Frederick T. Smith (703) 494-6500



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number

Fine Agrochemicals Ltd., Hill End House, Whittington, Worcester, WR5 2RQ, UK.
Phone 011 44 1905 361800

EPA Registration Number/File Symbol

62097-

Active Ingredient(s) and/or representative test compounds(s)

Indole-3-butyric Acid

Date

9/28/11

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)

Terrestrial food and non-food

Product Name

Indolebutyric Acid Technica

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

9/28/11

Typed or Printed Name and Title

Frederick T. Smith, Agent (SciReg, Inc.)

B 672

A B672 is described as a new product; non-food use or food use having established tolerance or tolerance exemption; unregistered source of active ingredient; no data compensation issues; all Tier I data requirements for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product-specific data or with request for data waivers supported by scientific rationales.

This PRIA code is interpreted as an application for registration of a microbial or biochemical pesticide product that is **not** substantially similar or identical in its uses and/or formulation to products that are currently registered. These applications require product specific chemistry data, acute toxicity data and other Tier I mammalian and non-target toxicity data as determined by the general use patterns for the product. When public health pests are claimed, efficacy (product performance) data for the product must be submitted.

End Use (EP) Data. Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA). This is for products with an unregistered source of active ingredient(s). These products are not 100% identical (repack)

Guideline No.	Product Chemistry Data Study Title	EP Data Submitted/ Cited		MP or TGA Data Submitted/ Cited	
		Yes	No	Yes	No
880.1100	Product Identity & Composition			✓	
880.1200	Description of starting materials production and formulation process.			✓	
880.1400	Discussion on the formation of impurities			✓	
830.1700	Preliminary analysis			✓	
830.1750	Certified limits (158.345)			✓	
830.1800	Enforcement analytical method			✓	
830.6302	Color			✓	
830.6303	Physical State			✓	
830.6304	Odor			✓	
830.6313	Stability to normal and elevated temperatures metal and metal ions			✓	
830.6315	Flammability			✓	
830.6317	Storage stability			✓	
830.6319	Miscibility			✓	
830.6320	Corrosion Characteristics			✓	
830.7000	pH			✓	
830.7050	UV/ Visible Absorption			✓	
830.7100	Viscosity			✓	
830.7200	Melting Point			✓	
830.7220	Boiling Point			✓	
830.7300	Density			✓	
830.7550	Partition Coefficient			✓	
830.7560					

830.7570				✓	
830.7840	Water Solubility			✓	
830.7950	Vapor Pressure			✓	

Grayed out = data not required

New products which are generated using an unregistered source of the active ingredient must either: 1) supply the product specific acute toxicity data (listed below), or 2) provide a bridging rationale document or a waiver request with a rationale. The bridging approach may be acceptable since the TGAi data is generated and submitted in addition to the end use data. If the inert components in the end use product are benign and do not significantly add to the ep such that the ep is significantly different from the MP thus changing the tox profile, a bridging argument may be deemed acceptable. This decision however, is made by the regulatory division.

End-use product Toxicity Data Requirements

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited		Waiver Request Rationale	
		Yes	No	Yes	No	Yes	No
870.1100	Acute Oral (LD50)						
870.1200	Acute Dermal (LD50)						
870.1300	Acute Inhalation (LC50)						
870.2400	Acute Eye Irritation						
870.2500	Acute Dermal Irritation						
870.2600	Dermal Sensitization						

Manufacturing Use Product (MP) or Technical Grade Active Ingredient (TGAi) Toxicity Data Requirements. The test substance must be the TGAi or MP

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited		Waiver Request Rationale	
		Yes	No	Yes	No	Yes	No
870.1100	Acute Oral (LD50)			✓			
870.1200	Acute Dermal (LD50)			✓			
870.1300	Acute Inhalation (LC50)			✓			
870.2400	Acute Eye Irritation			✓			
870.2500	Acute Dermal Irritation			✓			
870.2600	Dermal Sensitization			✓			
870.3100	90-day oral (one species					✓	

870.3250	90-day dermal - rat					✓	
870.3465	90-day inhalation - rat					✓	
870.3700	Prenatal Developmental - rat preferably					✓	
870.5100	Bacterial Reverse Mutation Test			PL			
870.5300 870.5375	<i>In vitro</i> mammalian cell assay			✓			

Manufacturing Use Product (MP) or Technical Grade Active Ingredient (TGA) Non-target Organism Toxicity. The test substance must be the TGA or MP

Guideline No.	Non-Target Organism Acute Toxicity Study Title	Data submitted		Cited		Waiver Request Rationale	
		Yes	No	Yes	No	Yes	No
850.2100	Avian Acute Oral Toxicity			✓			
850.2200	Avian Dietary Toxicity			✓			
850.1075	Fish Acute Toxicity, Freshwater			✓			
850.1010	Aquatic Invertebrate Acute Toxicity, Freshwater				✓		
850.4100	Terrestrial Plant Toxicity, Seedling Emergence					✓	
850.4150	Terrestrial Plant Toxicity, Vegetative Vigor					✓	

Efficacy - Whether or not these data are submitted depends on the proposed label use (public health pests). Data are conducted on the end-use product.



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Form Approved OMB No. 2070-0047

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DATA MATRIX

Date <u>9/28/11</u>	EPA Reg No./File Symbol <u>62097-</u>	Page <u>1</u> of <u>1</u>			
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd Hill End House Whittington, Worcester WR5 2RQ, UK		Product Indolebutyric Acid Technical			
Ingredient Indole-3-butyric acid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product identity and composition		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1600	Desc. of mat. used to produce the product		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1620	Desc. of production process		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1670	Discussion of formation of impurities		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1700	Preliminary analysis		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1750	Certified limits		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1800	Enforcement analytical method		Fine Agrochemicals Ltd.	OWN	Submitted herein
830 series	Physical and chemical properties	47124502	Zhejiang Tide Cropscience	PAY	
830.7050	UV/visible absorption		Fine Agrochemicals Ltd.	OWN	Submitted herein
870.1100 (152-10)	Acute oral toxicity	47124509	Zhejiang Tide Cropscience	PAY	
870.1200 (152-11)	Acute dermal toxicity	47124513	Zhejiang Tide Cropscience	PAY	
870.1300 (152-12)	Acute inhalation toxicity	47124514	Zhejiang Tide Cropscience	PAY	
870.2400 (152-13)	Primary eye irritation	47124510	Zhejiang Tide Cropscience	PAY	
870.2500 (152-14)	Primary dermal irritation	41863002	Syntex	OLD	
870.2600 (152-15)	Dermal sensitization	42483701	Syntex	OLD	
870.3100	90 day oral		Fine Agrochemicals Ltd.	OWN	Submitted herein
870.3250	90 day dermal		Fine Agrochemicals Ltd.	OWN	Submitted herein
870.3465	90 day inhalation		Fine Agrochemicals Ltd.	OWN	Submitted herein
870.3700 (152-23)	Teratogenicity		Fine Agrochemicals Ltd.	OWN	Submitted herein
870.5100	Bacterial mutation			PL	Refer to IBA Summary Document; specific PL referenced by EPA not available.
870.5300	In vitro mammalian cell assay	40898201 41011401	Merck Merck	OLD OLD	
850.2100 (154-6)	Avian acute oral toxicity	43026701	Indole-3-butyric Acid Task Force	OLD	
850.2200 (154-7)	Avian dietary toxicity	47124505	Zhejiang Tide Cropscience	PAY	
		43026702	Indole-3-butyric Acid Task Force	OLD	
		43026703	Indole-3-butyric Acid Task Force	OLD	
		43026704	Indole-3-butyric Acid Task Force	OLD	
850.1075 (154-8)	Freshwater fish LC50	42980501	BASF Sparks	OLD	
850.1300 (154-9)	Freshwater invertebrate LC50	42980502	BASF Sparks	OLD	
850.4100	Seedling emergence		Fine Agrochemicals Ltd.	OWN	Submitted herein
850.4150	Vegetative vigor		Fine Agrochemicals Ltd.	OWN	Submitted herein
Signature <u>Frederick T. Smith</u>			Name and Title Frederick T. Smith (Agent)		Date 9/28/11 106



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DATA MATRIX

Date <u>9/28/11</u>		EPA Reg. No./File Symbol <u>62097-</u>		Page <u>1</u> of <u>1</u>	
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House Whittington, Worcester WR5 2RQ, UK		Product Indolebutyric Acid Technical			
Ingredient Indole-3-butyric acid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Zhejiang Tide Cropscience	PAY	
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Zhejiang Tide Cropscience	PAY	
			Zhejiang Tide Cropscience	PAY	
			Zhejiang Tide Cropscience	PAY	
			Zhejiang Tide Cropscience	PAY	
			Syntex	OLD	
			Syntex	OLD	
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
				PL	Refer to IBA Summary Document; specific PL referenced by EPA not available.
			Merck	OLD	
			Merck	OLD	
			Indole-3-butyric Acid Task Force	OLD	
			Zhejiang Tide Cropscience	PAY	
			Indole-3-butyric Acid Task Force	OLD	
Indole-3-butyric Acid Task Force	OLD				
Indole-3-butyric Acid Task Force	OLD				
BASF Sparks	OLD				
BASF Sparks	OLD				
Fine Agrochemicals Ltd.	OWN	Submitted herein			
Fine Agrochemicals Ltd.	OWN	Submitted herein			
Signature <u>Frederick T. Smith</u>			Name and Title Frederick T. Smith (Agent)		Date <u>9/28/11</u>



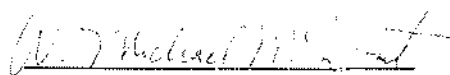
Indole-3-Butyric Acid
Preliminary Workplan and Summary Document

Registration Review: Initial Docket
September 2010

Case 2330

PC Code
046701

Approved by:


W. Michael McDavit
Acting Director, Biopesticides and
Pollution Prevention Division

9-16-10

Date

Study Type/OCSP Guideline	LD ₅₀ /LC ₅₀ /Results	Toxicity Category	Source
	Male acute LD ₅₀ >3,800mg/kg ¹ (rat); Female acute LD ₅₀ >5,800 mg/kg (rat)	III	4253390 t
Acute Inhalation Toxicity/OCSP 870.1300	Acute inhalation LC ₅₀ > 2.32 mg/L (rat)	IV	47124514
Acute Eye Irritation/OCSP 870.2400	Minimal effects clearing in less than 24 hours (rabbit)	IV	47124510
	Corneal involvement and/or irritation clearing in 8-21 days (rabbit) (see discussion below)	II	4186300 t
Acute Dermal Irritation/OCSP 870.2500	No irritation at 72 hours (rabbit)	IV	47124512
	No irritation at 72 hours (rabbit)	IV	41863002
Skin Sensitization/OCSP 870.2600	Not a dermal sensitizer	EPA, 1992	47124511
90-day Oral OCSP 870.3100	Waived, based on negligible dietary exposures expected from the use of IBA on food and feed crops.		EPA, 1992
90-day Dermal – rat/OCSP 870.3250	Waived, based on the expected extremely low exposures to those involved in the use of products containing IBA (no purposeful application to the skin and no expected prolonged skin exposure due to PPE requirements for applicators/handlers).		EPA, 1992
90-day Inhalation – rat/OCSP 870.3465	Waived, based on the expected extremely low exposures to those involved in the use of products containing IBA (no repeated exposure to IBA as a gas, vapor, or aerosol).		EPA, 1992
Prenatal (developmental)/OCSP 870.3700	Waived, based on the expected extremely low exposures to those involved in the use of products containing IBA, and due to the negligible dietary exposures expected from the use of IBA on food and feed crops.		EPA, 1992
Mutagenicity: Bacterial Reverse Mutation Test (Ames)/OCSP 870.5100	Negative with and without metabolic activation in <i>Salmonella typhimurium</i> at concentrations of 1-2,000 µg/plate.		Kappas, 1988
Mutagenicity: <i>In vitro</i> Mammalian Cell Assay (mouse lymphoma)/OCSP 870.5300	Negative in V-79 Chinese hamster lung cell mammalian cell mutagenesis assay.		40898201
	Negative in Chinese hamster ovary cell <i>in vitro</i> assay for chromosomal aberrations.		4 t01140 t

¹ highest dose tested

The Agency has received three studies on IBA to fulfill the acute dermal toxicity requirement. Two of these studies were performed on rabbits and one was performed on rats. In each study, all animals survived the duration of the

